Licensing Manual for Reproductive Technology Centres

Council on Human Reproductive Technology

August 2007

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SECTION 1 – LICENSING SYSTEM

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 Food and 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 Food and 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 diagnosis (PGD)[2];

  (vi) sperm sorting technique[3];

  (vii) sperm washing;

  (viii) in vitro maturation of oocytes;

  (ix) gamete cryopreservation;

  (x) embryo cryopreservation;

  (xi) embryo donation;

  (xii) oocyte donation;

  (xiii) assisted hatching;

  (xiv) embryo micromanipulation (other than assisted

[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 PGD. A RT centre licensed to carry out PGD, and which intends to carry out tissue typing in conjunction with PGD, 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 PGD. The principles set out in the "Ethical Guidelines on Pre-implantation Genetic Diagnosis" 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).

hatching);

(xv) sex selection;

(xvi) surrogacy arrangement.

3.7 The Secretary for Food and 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 Food and Health in a Gazette notice to be embryo research;

(c) excludes a procedure specified by the Secretary for Food and 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 Food and 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.

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 diagnosis 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;
(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)*

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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);
(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 PGD, and which intends to carry out tissue typing in conjunction with PGD, 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 PGD. The applicant should also observe the "Ethical Guidelines on Pre-implantation Genetic Diagnosis" 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 A change in any information provided pursuant to paragraphs. 6.2, 6.3, 6.4, 6.5, 6.6 and 6.7 above should be reported to the Council within 28 days after the occurrence of the change. 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)*

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)

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)*

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).

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 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 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 attached as Annexes 1, 3, 5 and 7 of this Manual for first-time applications and as Annexes 2, 4, 6 and 8 for licence renewals.

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

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

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 member of the Ethics Committee, 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) and a lay person. The inspection team may also include not more than three other experts who have expertise in carrying out inspection of the premises under application.

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 should be made by a crossed 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

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 as prescribed under the HRT (Fees) Regulation is set out below —

		Fee (In Hong Kong Dollars)			
Item	**Matter**	**AIH Licence**	**Treatment Licence**	**Research Licence**	**Storage Licence**
1.	Application for, or application for the renewal of a licence under section 21 of the Ordinance	$ 895	$ 1,200	$ 1,200	$ 1,200
2.	Grant or renewal of a licence under section 23(1)(a) of the Ordinance	$ 3,510	$ 6,110	$ 6,110	$ 6,110

		Fee (In Hong Kong Dollars)			
Item	**Matter**	**AIH Licence**	**Treatment Licence**	**Research Licence**	**Storage Licence**
3.	Application for variation of a licence under section 27(4) of the Ordinance	$ 3,470	$ 5,400	$ 5,400	$ 5,400
4.	Application for revocation of a licence under section 27(4) of the Ordinance	$ 2,300	$ 3,730	$ 3,730	$ 3,730
5.	Issue of an exact copy of a licence for the purposes of section 30 of the Ordinance	$ 555	$ 555	$ 555	$ 555
6.	Issue of a licence in like terms as those contained in a lost, defaced or destroyed licence under section 31 of the Ordinance	$ 555	$ 555	$ 555	$ 555

Annex 1

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

APPLICATION FOR AIH LICENCE (FIRST-TIME APPLICATION)
夫精人工授精牌照申請書(首次申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

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

The completed form should be returned together with supporting documentation and the application fee of HK$895 to:
填妥後的申請書須連同證明文件及申請費用港幣 895 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form. The name of licence applicant, the address of the premises where relevant activities are intended to be carried out and the class of licence applied for will be published in the website of the Council on Human Reproductive Technology for public access.
* 本申請書末頁載有填寫須知，可供參考。公眾人士可在人類生殖科技管理局網頁內查閱牌照申請人的姓名/名稱，擬進行有關活動的處所地址及所申請的牌照類別。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the artificial insemination by husband (AIH) procedures are intended to be carried out belong to the following class (please tick the appropriate box):
擬進行夫精人工授精程序的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐

(c) a public hospital as defined in section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施	☐	**Private** 私營機構	☐	**Other institutions** 其他機構	☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：
HKID Card / Passport No. :
香港身分證/護照號碼：
Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：
HKID Card / Passport No. :
香港身分證/護照號碼：
Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Information about AIH and related services to be offered 擬提供的夫精人工授精服務及相關服務的資料

5.1 Date centre opened:
中心開業日期： _____

5.2 Date centre first offered AIH:
中心擬首次提供夫精人工授精服務的日期： _____

5.3 Type(s) of AIH to be offered (Please tick the appropriate box(es)) :
擬提供的夫精人工授精服務的種類(請在適當方格加上✓號)：

		Yes 有	No 沒有
(a)	**Intravaginal 陰道內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐
(b)	**Intracervical 宮頸內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐
(c)	**Intrauterine 子宮內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐

5.4 Does the centre provide semen/ sperm storage for patients? (Please tick the appropriate box) 中心有沒有為病人提供精液/精子儲存服務？(請在適當方格加上✓號)

Yes 有 ☐ **No 沒有** ☐

5.5 Will the centre use the facilities/ services of other centres, clinics or practitioners for carrying out AIH? (Please tick the appropriate box)
中心會不會使用其他中心、診所或醫生的設施/服務以施行夫精人工授精程序？(請在適當方格加上✓號)

Yes 會 ☐ **No 不會** ☐

If the answer is **yes**, please provide the details of the facilities/ services and of the centres/ clinics/ practitioners who will be providing them:
如會，請就該等設施/服務及提供該等設施/服務的中心/診所/醫生提供有關詳情：

Details of facilities/services to be used:
擬使用的設施/服務詳情：_____

Name of centre/ clinic/ practitioner providing the facilities/ services:
提供該等設施/服務的中心/診所/醫生的名稱或姓名：_____

Address 地址：_____

_____

_____

_____

Tel No. 電話號碼：_____

Fax No. 傳真號碼：_____

E-mail address (if applicable):
電郵地址(如適用)：_____

Website address (if applicable):
網址(如適用)：_____

Contact person 聯絡人：_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

6. Staff 職員

6.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed below.
請列明中心內擔任下列職位的職員，並就下表所列全部職員提供履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
.....	Proposed Licensee 準持牌人	See CV 見履歷表
.....	Proposed Person Responsible 準負責人	See CV 見履歷表
.....	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
.....	Counsellor in charge 主任輔導員	See CV 見履歷表

6.2 Please list below all other staff members in the centre involved in the treatment of patients or who have access to patient records.
請列明中心內參與治療病人或會接觸病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
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.....	.....	.....

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Supporting Documentation 證明文件

7.1 In order to process this application it is essential that the Council be provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

7.2 CVs for each of the staff listed in section 6.1 (marked collectively as Appendix A). They may include:
第 6.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Nurse Co-ordinator 護士統籌主任
(d) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

7.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

7.4 One complete set of all consent forms to be used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

7.5 One complete set of all treatment record forms to be used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部治療記錄表格的整套資料一份，包括問卷(一律標明為附錄 D)。

7.6 One complete set of all standard operating procedures and protocols to be used by the centre, including procedures and protocols appertaining to assessment of patients, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與病人評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

7.7 One copy of contingency plan to be adopted by the centre (marked as Appendix F).
中心所用應變計劃的複本一份(標明為附錄 F)。

8. Additional Information 其他資料

8.1 Is there any other information regarding your centre which you may wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed in this form? If so, please give details below.
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

8.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

9. Declarations 聲明

9.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

9.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

9.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

9.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing AIH Licence Application Form
夫精人工授精牌照申請書填寫須知
(First-time Application)
(首次申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章)第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分:
This section contains a list of relevant activities governed by the Human Reproductive Technology Ordinance (Cap. 561).
此部分載列《人類生殖科技條例》(第 561 章) 所規管的有關活動。

Section 6
第 6 部分:
All staff who will be directly involved in the treatment of patients or who have access to patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與治療病人或會接觸病人記錄的全部職員及其職位。

Section 9
第 9 部分:
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 2

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

APPLICATION FOR AIH LICENCE (RENEWAL)
夫精人工授精牌照申請書(續期申請)

Name of Centre in English:……
中心名稱 (英文)：

Name of Centre in Chinese: ..……
中心名稱 (中文)：

Licence Number: …….
牌照號碼：

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

The completed form should be returned together with supporting documentation and the application fee of HK$895 to:
填妥的申請書須連同證明文件及申請費用港幣 895 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form.
* 本申請書末頁載有填寫須知，可供參考。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the artificial insemination by husband (AIH) procedures are intended to be carried out belong to the following class (please tick the appropriate box):
擬進行夫精人工授精程序的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343) ☐
根據《診療所條例》(第 343 章)註冊的診療所

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) ☐
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113) ☐
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施	☐	**Private** 私營機構	☐	**Other institutions** 其他機構	☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

2.3 Has the ownership (or the **controlling interest**) of the centre changed in the past year? (Please tick the appropriate box)
中心的擁有權(或**控制權益**)在過去一年有沒有改變？(請在適當方格加上✓號)

Yes 有 ☐ **No** 沒有 ☐

If yes, please give details below 如有，請在下面詳加說明：

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Information about AIH and related services offered 所提供的夫精人工授精服務及相關服務的資料

5.1 Please give the date licensed AIH treatment was first offered at the centre:
中心首次提供夫精人工授精服務的日期：

_____

5.2 Type(s) of AIH to be offered (Please tick the appropriate box(es)) :
所提供的夫精人工授精服務的種類(請在適當方格加上✓號)：

	Yes 有	**No 沒有**
(a) **Intravaginal 陰道內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐
(b) **Intracervical 宮頸內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐
(c) **Intrauterine 子宮內授精** involving ovarian stimulation with gonadotrophins 涉及使用促性腺激素刺激卵巢	☐	☐

5.3 Does the centre provide semen/ sperm storage for patients? (Please tick the appropriate box) 中心有沒有為病人提供精液/精子儲存服務？(請在適當方格加上✓號)

Yes 有 ☐ **No** 沒有 ☐

5.4 Will the centre use the facilities/ services of other centres, clinics or practitioners for carrying out AIH? (Please tick the appropriate box)
中心會不會使用其他中心、診所或醫生的設施/服務以施行夫精人工授精程序？(請在適當方格加上✓號)

Yes 會 ☐ **No** 不會 ☐

If the answer is **yes**, please provide the details of the facilities/ services and of the centres/ clinics/ practitioners who will be providing them:
如會，請就該等設施/服務及提供該等設施/服務的中心/診所/醫生提供有關詳情：

Details of facilities/ services to be used:
擬使用的設施/服務詳情：_____

Name of centre/ clinic/ practitioner providing the facilities/ services:
提供該等設施/服務的中心/診所/醫生的名稱或姓名：_____

Address 地址：_____

_____

_____

_____

Tel No. 電話號碼：_____

Fax No. 傳真號碼：_____

E-mail address (if applicable):
電郵地址(如適用)：_____

Website address (if applicable):
網址(如適用)：_____

Contact person 聯絡人：_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

6. Staff 職員

6.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed below.
請列明中心內擔任下列職位的職員，並就下表所列全部職員提供履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	Proposed Licensee 準持牌人	See CV 見履歷表
……	Proposed Person Responsible 準負責人	See CV 見履歷表
……	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
……	Counsellor in charge 主任輔導員	See CV 見履歷表

6.2 Please list below all other staff members in the centre involved in the treatment of patients or who have access to patient records.
請列明中心內參與治療病人或會接觸病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Supporting Documentation 證明文件

7.1 In order to process this application it is essential that the Council be provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

7.2 CVs for each of the staff listed in section 6.1 (marked collectively as Appendix A). They may include:
第 6.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Nurse Co-ordinator 護士統籌主任
(d) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

7.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

7.4 One complete set of all consent forms used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

7.5 One complete set of all treatment record forms used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部治療記錄表格的整套資料一份，包括問卷(一律標明為附錄 D)。

7.6 One complete set of all standard operating procedures and protocols used by the centre, including procedures and protocols appertaining to assessment of patients, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與病人評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

7.7 One copy of contingency plan to be adopted by the centre (marked as Appendix F).
中心所用應變計劃的複本一份(標明為附錄 F)。

8. Additional Information 其他資料

8.1 Is there any other information regarding your centre which you may wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed in this form? If so, please give details below.
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

8.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

9. Declarations 聲明

9.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章)第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

9.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

9.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

9.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing AIH Licence Application Form
夫精人工授精牌照申請書填寫須知
(Renewal Application)
(續期申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章)第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分:
This section contains a list of relevant activities governed by the Human Reproductive Technology Ordinance (Cap. 561).
此部分載列《人類生殖科技條例》(第 561 章)所規管的有關活動。

Section 6
第 6 部分:
All staff who will be directly involved in the treatment of patients or who have access to patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與治療病人或會接觸病人記錄的全部職員及其職位。

Section 9
第 9 部分:
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 3

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

APPLICATION FOR TREATMENT LICENCE (FIRST-TIME APPLICATION)
治療牌照申請書(首次申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

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

The completed form should be returned together with supporting documentation and the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form. The name of licence applicant, the address of the premises where relevant activities are intended to be carried out and the class of licence applied for will be published in the website of the Council on Human Reproductive Technology for public access.
* 本申請書末頁載有填寫須知，可供參考。公眾人士可在人類生殖科技管理局網頁內查閱牌照申請人的姓名/名稱，擬進行有關活動的處所地址及所申請的牌照類別。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the reproductive technology procedures are intended to be carried out belong to the following class (please tick the appropriate box) :
擬進行生殖科技程序的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343) ☐
根據《診療所條例》(第 343 章)註冊的診療所

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) ☐
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113) ☐
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施 ☐ **Private** 私營機構 ☐ **Other institutions** 其他機構 ☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

5. Details of Accredited Specialist 認可專家資料

Name 姓名： _____

Position 職位： _____

6. Information about treatments to be offered 擬提供的治療的資料

6.1 Date centre opened 中心開業日期： _____

6.2 Date centre first offered treatment:
中心擬首次提供治療的日期： _____

6.3 Please tick the appropriate boxes below to indicate the treatment services for which the centre wishes to be licensed:
請在下列適當方格加上✓號，以說明中心擬領牌提供的治療服務：

Treatment services *治療服務*	*To be included in licence* *擬納入牌照的治療服務*
In vitro fertilization (IVF) 體外受精	
Artificial insemination by husband (AIH) 夫精人工授精	
Artificial insemination by donor (AID)/ Donor insemination (DI) 他精人工授精	
Removal of oocytes from ovaries 從卵巢取出卵母細胞	
Retrieval of sperm from testis 從睪丸取出精子	
Retrieval of sperm from epididymis 從附睪取出精子	
Frozen-thawed/ fresh embryo transfer (ET) 凍融/新鮮胚胎移植	
Microinjection intra-fallopian transfer (MIFT) 顯微注射輸卵管內移植	
Fallopian replacement of eggs with delayed insemination (FREDI) 輸卵管內置放卵子後進行授精	
Intra cytoplasmic sperm injection (ICSI) 細胞漿內精子注入法	
Pre-implantation genetic diagnosis (PGD)[1] 植入前基因診斷 [1]	
Sperm sorting technique[2] 精子分類技術 [2]	
Sperm washing 精子洗滌	
In vitro maturation of oocytes 卵母細胞體外成熟	
Storage of semen/sperm (donor/patient*) 儲存精液/精子(捐贈人/病人*)	
Storage of oocyte (donor/ patient*) 儲存卵母細胞(捐贈人/病人*)	
Storage of embryo (donor/patient*) 儲存胚胎(捐贈人/病人*)	

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

[1] A treatment licence may grant general permission for RT centre to carry out PGD. RT centre licensed to carry out PGD and which intends to carry out tissue typing in conjunction with PGD is required to submit an application form (Annex 9 of the "Licensing Manual for Reproductive Technology Centres") together with a clinical report to the Council to seek prior approval on a case-by-case basis before commencement of each treatment involving tissue typing in conjunction with PGD. The principles of the "Ethical Guidelines on Pre-implantation Genetic Diagnosis" in the Code should be followed.

[1] 治療牌照可就生殖科技中心進行植入前基因診斷給予一般許可。獲發牌照進行植入前基因診斷的生殖科技中心如擬把植入前基因診斷與組織分型結合使用，須向管理局提交申請書(《供生殖科技中心參考的發牌手冊》 附件 9)及臨牀報告，以就每宗涉及把植入前基因診斷與組織分型結合使用的治療逐一徵求事先批准，並須遵照《實務守則》附錄「植入前基因診斷倫理指引」中訂明的原則。

[2] 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).

[2] 精子分類技術指:「擬將帶有 Y 染色體(將會製造男性胚胎)的精子和帶有 X 染色體(將會製造女性胚胎)的精子分隔的技術。」

Treatment services *治療服務*	*To be included in licence* *擬納入牌照的治療服務*
Storage of testicular tissue[3] 儲存睪丸組織 [3]	
Storage of ovarian tissue[3] 儲存卵巢組織 [3]	
Embryo donation 胚胎捐贈	
Oocyte donation 卵母細胞捐贈	
Assisted hatching 輔助孵化	
Embryo micromanipulation (other than assisted hatching) 顯微操控胚胎技術(輔助孵化除外)	
Sex selection 性別選擇	
Surrogacy arrangement 代母安排	
Other micromanipulation (please specify) 其他顯微操控技術(請註明)	
Others (please specify) 其他(請註明)	

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

6.4 Will the facilities/ services of the centre be used by other centres, clinics or practitioners for carrying out treatment procedures or other supporting services? (Please tick the appropriate box)
中心的設施/服務會否供其他中心、診所或醫生使用以進行治療程序或提供其他支援服務？(請在適當方格加上✓號)

Yes 會 ☐ **No 不會** ☐

[3] Storage of testicular and ovarian tissue will require a licence only if gametes are present in the tissue. The Council works according to the following definition of gametes: "Gametes refer to 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".

[3] 儲存含有配子的睪丸和卵巢組織必須領牌。管理局行事時所依據的配子定義為：「配子指生殖細胞，即男性的精子和女性的卵子；精子及卵子融合後便形成合子。每個人類配子包含內有 23 個染色體的基本組合(單倍體的組合)。卵子與精子融合時，便成為內有 46 個染色體的完整組合(雙倍體組合)。其他所有軀體細胞的細胞核，均含有 46 個染色體。」

If the answer is **yes**, please provide the details of the facilities/services and of the centres/ clinics/ practitioners who will be using them:
如**會**，請就該等設施/服務及將會使用該等設施/服務的相關中心/診所/醫生提供有關詳情：

Details of facilities/services to be used:
擬使用的設施/服務詳情：

Name of centre/ clinic/ practitioner using the facilities/ services:
使用該等設施/服務的中心/診所/醫生的名稱或姓名：

Address 地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable) :
電郵地址(如適用):

Website address (if applicable) :
網址(如適用)：

Contact person 聯絡人：

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Staff 職員

7.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed below.
請列明中心內擔任下列職位的職員，並就下表所列全部職員提交履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	Proposed Licensee 準持牌人	See CV 見履歷表
……	Proposed Person Responsible 準負責人	See CV 見履歷表
……	Accredited Specialist 認可專家	See CV 見履歷表
……	Embryologist in charge 主任胚胎學家	See CV 見履歷表
……	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
……	Counsellor in charge 主任輔導員	See CV 見履歷表

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.2 Please list below all staff members in the centre involved in the treatment of patients or who have access to patient records.
請列明中心內參與治療病人或會接觸病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
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……	……	……
……	……	……

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.3 Please provide the details of the centre's complaint officer.
請提供中心內投訴主任的資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……

8. Supporting Documentation 證明文件

8.1 In order to process this application it is essential that the Council be provided with a full set of the appropriate supporting documentation. This should include all agreements signed with the related centres, clinics or practitioners listed in paragraph 6.4. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。文件應包括與第 6.4 段所列相關中心、診所或醫生所簽訂的全部協議書。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

8.2 CVs for each of the staff listed in paragraph 7.1 (marked collectively as Appendix A). They may include:
第 7.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Accredited Specialist(s) 認可專家
(d) Embryologist in charge 主任胚胎學家
(e) Nurse Co-ordinator 護士統籌主任
(f) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

8.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

8.4 One complete set of all consent forms to be used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

8.5 One complete set of all treatment record forms to be used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部治療記錄表格的整套資料一份，包括問卷(一律標明為附錄 D)。

8.6 One complete set of all standard operating procedures and protocols to be used by the centre, including procedures and protocols appertaining to assessment of patients/donors, assessment of the welfare of the child, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與病人/捐贈人評估、兒童福利評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

8.7 One copy of all agreements signed with related centres, clinics or practitioners listed in paragraph 6.4 (marked collectively as Appendix F).
中心與第 6.4 段所列相關中心、診所或醫生所簽訂全部協議書的整套文件一份(一律標明為附錄 F)。

8.8 One copy of contingency plan to be adopted by the centre (marked as Appendix G).
中心所用應變計劃的複本一份(標明為附錄 G)。

9. Additional Information 其他資料

9.1 Is there any other information regarding your centre which you may wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed in this form? If so, please give details below.
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

_____

_____

_____

_____

_____

_____

9.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

_____

_____

_____

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Declarations 聲明

10.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

10.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

10.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

10.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Accredited Specialist 認可專家

10.5 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the accredited specialist.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任認可專家。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Treatment Licence Application Form
治療牌照申請書填寫須知
(First-time Application)
(首次申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分：
The accredited specialist is the medical practitioner who holds the overall clinical responsibility.
認可專家即承擔整體臨牀責任的醫生。

Section 6
第 6 部分：
This section contains a list of relevant activities governed by the Human Reproductive Technology Ordinance (Cap. 561). Centre must indicate the reproductive technology services for which it wishes to be licensed.
此部分載列《人類生殖科技條例》(第 561 章) 所規管的有關活動。中心必須列明擬領牌照的生殖科技服務。

Section 7
第 7 部分：
All staff who will be directly involved in the treatment of patients or who have access to patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與治療病人或會接觸病人記錄的全部職員及其職位。

Section 10
第10部 分：
When signing the declarations section, the following should be noted:

(a) If the proposed person responsible is also the accredited specialist, he or she should sign both sections;
(b) If the proposed person responsible is also the applicant, he or she should sign both sections.

在簽署聲明時，請注意下列各項：

(a) 準負責人如同時亦是認可專家，則應簽署聲明中兩個相關部分；
(b) 準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 4

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

APPLICATION FOR TREATMENT LICENCE (RENEWAL)
治療牌照申請書 (續期申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

Licence Number: ...……
牌照號碼：

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

The completed form and all supporting documents should be returned together with the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form.
* 本申請書末頁載有填寫須知，可供參考。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable) :
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the reproductive technology procedures are intended to be carried out belong to the following class (please tick the appropriate box) :
擬進行生殖科技程序的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343) ☐
根據《診療所條例》(第 343 章)註冊的診療所

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) ☐
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113) ☐
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施 ☐ **Private** 私營機構 ☐ **Other institutions** 其他機構 ☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：
HKID Card / Passport No. :
香港身分證/護照號碼：
Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：
HKID Card / Passport No. :
香港身分證/護照號碼：
Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

2.3 Has the ownership (or the **controlling interest**) of the centre changed in the past year? (Please tick the appropriate box)
中心的擁有權(或**控制權益**)在過去一年有沒有改變？(請在適當方格加上✓號)

Yes 有 ☐ **No 沒有** ☐

If yes, please give details below 如有，請在下面詳加說明：

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Details of Accredited Specialist 認可專家資料

Name 姓名： _____

Position 職位： _____

6. Information about treatments to be offered 所提供的治療的資料

6.1 Please give the date licensed infertility treatments were first offered at the centre:
請列出中心首次提供領牌不育治療的日期：

_____

6.2 Please tick the appropriate boxes below to indicate the treatment services for which the centre is currently licensed plus those treatment services which the centre wishes to include in the renewal licence:
請在下列適當方格加上✓號，以說明中心現已領牌及現擬納入續期牌照的治療服務：

Treatment services *治療服務*	*Existing licensed treatment services* *現已領牌的治療服務*	*Treatment services to be included in renewal licence (including existing licensed treatment services)* *現擬納入續期牌照的治療服務(包括現已領牌的治療服務)*
In vitro fertilization (IVF) 體外受精		
Artificial insemination by husband (AIH) 夫精人工授精		
Artificial insemination by donor (AID)/ Donor insemination (DI) 他精人工授精		
Removal of oocytes from ovaries 從卵巢取出卵母細胞		
Retrieval of sperm from testis 從睪丸取出精子		
Retrieval of sperm from epididymis 從附睪取出精子		
Frozen-thawed/ fresh embryo transfer (ET) 凍融/新鮮胚胎移植		
Microinjection intra-fallopian transfer (MIFT) 顯微注射輸卵管內移植		
Fallopian replacement of eggs with delayed insemination (FREDI) 輸卵管內置放卵子後進行授精		
Intra cytoplasmic sperm injection (ICSI) 細胞漿內精子注入法		
Pre-implantation genetic diagnosis (PGD)[1] 植入前基因診斷[1]		
Sperm sorting technique[2]		

[1] A treatment licence may grant general permission for RT centre to carry out PGD. RT centre licensed to carry out PGD and which intends to carry out tissue typing in conjunction with PGD is required to submit an application form (Annex 9 of the "Licensing Manual for Reproductive Technology Centres") together with a clinical report to the Council to seek prior approval on a case-by-case basis before commencement of each treatment involving tissue typing in conjunction with PGD. The principles of the "Ethical Guidelines on Pre-implantation Genetic Diagnosis" in the Code should be followed.

[1] 治療牌照可就生殖科技中心進行植入前基因診斷給予一般許可。獲發牌照進行植入前基因診斷的生殖科技中心如擬把植入前基因診斷與組織分型結合使用，須向管理局提交申請書(《供生殖科技中心參考的發牌手冊》 附件 9)及臨牀報告，以就每宗涉及把植入前基因診斷與組織分型結合使用的治療逐一徵求事先批准，並須遵照《實務守則》附錄「植入前基因診斷倫理指引」中訂明的原則。

[2] Sperm sorting technique means a technique intended to separate sperm carrying a Y chromosome (which

Treatment services *治療服務*	*Existing licensed treatment services* *現已領牌的治療服務*	*Treatment services to be included in renewal licence (including existing licensed treatment services)* *現擬納入續期牌照的治療服務(包括現已領牌的治療服務)*
精子分類技術 [2]		
Sperm washing 精子洗滌		
In vitro maturation of oocytes 卵母細胞體外成熟		
Storage of semen/ sperm (donor/ patient*) 儲存精液/精子(捐贈人/病人*)		
Storage of oocyte (donor/ patient*) 儲存卵母細胞(捐贈人/病人*)		
Storage of embryo (donor/ patient*) 儲存胚胎(捐贈人/病人*)		
Storage of testicular tissue[3] 儲存睪丸組織 [3]		
Storage of ovarian tissue[3] 儲存卵巢組織 [3]		
Embryo donation 胚胎捐贈		
Oocyte donation 卵母細胞捐贈		
Assisted hatching 輔助孵化		
Embryo micromanipulation (other than assisted hatching) 顯微操控胚胎技術(輔助孵化除外)		
Sex selection 性別選擇		
Surrogacy arrangement 代母安排		
Other micromanipulation (please specify) 其他顯微操控技術(請註明)		

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

Others (please specify) 其他(請註明)		

would create a male embryo) from sperm carrying X chromosome (which would create a female embryo).

[2] 精子分類技術指:「擬將帶有 Y 染色體(將會製造男性胚胎)的精子和帶有 X 染色體(將會製造女性胚胎)的精子分隔的技術。」

[3] Storage of testicular and ovarian tissue will require a licence only if gametes are present in the tissue. The Council works according to the following definition of gametes: "Gametes refer to 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".

[3] 儲存含有配子的睪丸和卵巢組織必須領牌。管理局行事時所依據的配子定義為:「配子指生殖細胞,即男性的精子和女性的卵子;精子及卵子融合後便形成合子。每個人類配子包含內有 23 個染色體的基本組合(單倍體的組合)。卵子與精子融合時,便成為內有 46 個染色體的完整組合(雙倍體組合)。其他所有軀體細胞的細胞核,均含有 46 個染色體。」

Treatment services *治療服務*	*Existing licensed treatment services* *現已領牌的治療服務*	*Treatment services to be included in renewal licence (including existing licensed treatment services)* *現擬納入續期牌照的治療服務(包括現已領牌的治療服務)*

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

6.3 Will the facilities/ services of the centre be used by other centres, clinics or practitioners for carrying out treatment procedures or other supporting services? (Please tick the appropriate box)
中心的設施/服務會否供其他中心、診所或醫生使用以進行治療程序或提供其他支援服務？(請在適當方格加上✓號)

Yes 會 ☐ **No 不會** ☐

If the answer is **yes**, please provide the details of the facilities/ services and of the centres/ clinics/ practitioners who will be using them:
如**會**，請就該等設施/服務及將會使用該等設施/服務的相關中心/診所/醫生提供有關詳情：

Details of facilities/ services to be used:
擬使用的設施/服務詳情：_____

Name of centre/ clinic/ practitioner using the facilities/ services:
使用該等設施/服務的中心/診所/醫生的名稱或姓名：_____

Address 地址：_____

_____

_____

_____

Tel No. 電話號碼：_____

Fax No. 傳真號碼：_____

E-mail address (if applicable) :
電郵地址(如適用)：_____

Website address (if applicable) :
網址(如適用)：_____

Contact person 聯絡人：_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Staff 職員

7.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed below.
請列明中心內擔任下列職位的職員，並就下表所列全部職員提交履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
……	Proposed Licensee 準持牌人	See CV 見履歷表
……	Proposed Person Responsible 準負責人	See CV 見履歷表
……	Accredited Specialist 認可專家	See CV 見履歷表
……	Embryologist in charge 主任胚胎學家	See CV 見履歷表
……	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
……	Counsellor in charge 主任輔導員	See CV 見履歷表

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.2 Please list below all other staff members in the centre involved in the treatment of patients or who have access to patient records.
請列明中心內參與治療病人或會接觸病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/ 職位*	*Qualification/Experience* *資格/ 經驗*
……	……	……
……	……	……
……	……	……
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Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.3 Please provide the details of the centre's complaint officer.
請提供中心內投訴主任的資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……

8. Supporting Documentation 證明文件

8.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. This should include all agreements signed with the related centres, clinics or practitioners listed in paragraph 6.3. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。文件應包括與第 6.3 段所列相關中心、診所或醫生所簽訂的全部協議書。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

8.2 CVs for each of the staff listed in paragraph 7.1 (marked collectively as Appendix A). They may include:
第 7.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括:

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Accredited Specialist(s) 認可專家
(d) Embryologist in charge 主任胚胎學家
(e) Nurse Co-ordinator(s) 護士統籌主任
(f) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

8.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

8.4 One complete set of all consent forms used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

8.5 One complete set of all treatment record forms used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部治療記錄表格的整套資料一份，包括問卷(一律標明為附錄 D)。

8.6 One complete set of all standard operating procedures and protocols used by the centre, including procedures and protocols appertaining to assessment of patients/donors, assessment of the welfare of the child, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與病人/捐贈人評估、兒童福利評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

8.7 One copy of all agreements signed with related centres, clinics or practitioners listed in paragraph 6.3 (marked collectively as Appendix F).
中心與第 6.3 段所列相關中心、診所或醫生所簽訂全部協議書的整套文件一份(一律標明為附錄 F)。

8.8 One copy of contingency plan to be adopted by the centre (marked as Appendix G).
中心所用應變計劃的複本一份(標明為附錄 G)。

9. Special Conditions 特別條件

9.1 Details of the action taken to address any special conditions specified by the Council, applicable to the current licence, should be given below.
中心因應管理局所指明並適用於現行牌照的任何特別條件而採取的行動，請在下面詳加說明。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Additional Information 其他資料

10.1 Is there any other information regarding your centre which you wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed in this form? If so, please give details below.
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

10.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

_____

_____

_____

_____

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

11. Declarations 聲明

11.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

11.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

11.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

11.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Accredited Specialist 認可專家

11.5 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the accredited specialist.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任認可專家。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Treatment Licence Application Form
治療牌照申請書填寫須知
(Renewal Application)
(續期申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分：
The accredited specialist is the medical practitioner who holds the overall clinical responsibility.
認可專家即承擔整體臨牀責任的醫生。

Section 6
第 6 部分：
This section contains a list of relevant activities governed by the Human Reproductive Technology Ordinance (Cap. 561). Centre must indicate those licensed reproductive technology services for which it wishes to renew plus those it wishes to include in the new licence.
此部分載列《人類生殖科技條例》(第 561 章) 所規管的相關活動。中心必須列明擬續牌提供及擬納入新牌照的生殖科技服務。

Section 7
第 7 部分：
All staff who will be directly involved in the treatment of patients or who have access to patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與治療病人或會接觸病人記錄的全部職員及其職位。

Section 11
第11部分：
When signing the declarations section, the following should be noted:

(a) If the proposed person responsible is also the accredited specialist, he or she should sign both sections;
(b) If the proposed person responsible is also the applicant, he or she should sign both sections.

在簽署聲明時，請注意下列各項：

(a) 準負責人如同時亦是認可專家，則應簽署聲明中兩個相關部分；
(b) 準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 5

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

APPLICATION FOR RESEARCH LICENCE (FIRST-TIME APPLICATION)
研究牌照申請書 (首次申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

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

The completed form should be returned together with supporting documentation and the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form. The name of licence applicant, the address of the premises where relevant activities are intended to be carried out and the class of licence applied for will be published in the website of the Council on Human Reproductive Technology for public access.

* 本申請書末頁載有填寫須知，可供參考。公眾人士可在人類生殖科技管理局網頁內查閱牌照申請人的姓名/名稱，擬進行有關活動的處所地址及所申請的牌照類別。

1. Details of the Centre Undertaking Research 進行研究的中心的資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the embryo research project is intended to be carried out belong to the following class (please tick the appropriate box):
擬進行有關胚胎研究項目的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號。)

Hospital Authority facility 醫院管理局轄下設施	☐	**Private** 私人機構	☐	**Other institutions** 其他機構	☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. :
香港身分證/護照號碼： _____

5. Title of Research Project 研究項目的名稱

5.1 Please give the full title of the project.
請提供擬領牌的研究項目的全稱。

_____

_____

_____

_____

_____

_____

5.2 If you have previously held a research licence for work in this area please give the project title(s) and research licence number(s).
如曾持有相關範疇的研究牌照，請提供該牌照所涉項目的名稱及牌照編號。

_____

_____

_____

_____

_____

_____

5.3 Please indicate the purpose(s) of research (as defined in paragraph 11.5 of the Code) the project falls under. You may tick more than one box.
請根據《生殖科技及胚胎研究實務守則》第 11.5 段所界定的類別，說明有關項目的研究目的。可選超過一個方格加上✓ 號。

(a) to promote advances in the treatment of infertility
促進不育治療的發展 ☐

(b) to increase knowledge about the causes or treatment of congenital disease
增進有關先天性疾病的成因或治療方面的知識 ☐

(c) to increase knowledge about the causes or treatment of miscarriages
增進有關流產問題的成因或治療方面的知識 ☐

(d) to develop more effective techniques of contraception
發展更有效的避孕方法 ☐

(e) to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation
發展技術，在胚胎植入母體前，偵察胚胎內基因或染色體的異常情況 ☐

(f) to increase knowledge about the development of embryos
增進有關胚胎發展的知識 ☐

(g) to increase knowledge about serious diseases
增進有關嚴重疾病的知識 ☐

(h) to enable such knowledge to be applied in the development of treatments to combat serious diseases
致使所得知識用於發展相關治療方法，以對抗嚴重疾病 ☐

(i) others (please specify)
其他(請註明) ☐

_____

_____

6. Duration of Project 研究項目的期限

6.1 Please give the proposed date of commencement for the project.
請提供研究項目的建議開始日期。

_____

_____

_____

6.2 Please indicate the period of time for which you wish the licence to be granted (not more than 3 years).
請說明希望獲批的牌照有效期(不超過 3 年)。

_____

_____

_____

7. Estimated Usage of Material 擬使用的物料

7.1 Please indicate in the boxes below the estimated numbers of oocytes and embryos you expect to use during the period of the licence. If more than one year has been requested please indicate the yearly usage in the appropriate boxes.
請於下列方格填寫預計會於牌照有效期內使用的卵母細胞及胚胎數目。如申請有效期超過一年的牌照，請在適當方格填上每年的使用數量。

Material 物料	**Year 1 第一年**	**Year 2 第二年**	**Year 3 第三年**
Fresh Oocytes 新鮮卵母細胞			
Frozen Oocytes 冷藏卵母細胞			
Failed to fertilize Oocytes 不能受精的卵母細胞			
Fresh Embryos 新鮮胚胎			
Frozen Embryos 冷藏胚胎			

8. Centre(s) Providing Gametes/Embryos 供應配子/胚胎的中心

8.1 Please give the names of the centres that will be supplying materials for this project, together with an indication of the number of embryos and/ or oocytes they each will be providing.
請提供將為擬領牌的研究項目供應物料的中心的名稱，並說明每一中心將會分別供應的胚胎及/或卵母細胞數量。

Name of Centre 中心名稱	**Semen Provided (Yes/ No) 供應精液 (是/否)**	**No. of Embryos Provided 所供應胚胎的數量**	**No. of Oocytes Provided 所供應卵母細胞的數量**

9. Current Research Projects 現有研究項目

9.1 If you currently hold a research licence, please give the licence number(s) and title(s) of current research projects below. If you do not currently hold a research licence, please proceed to section 10.
如現時持有研究牌照，請在下面提供該牌照的編號及現有研究項目的名稱。若現時並無持有任何研究牌照，請繼續填寫第 10 部分。

_____

_____

_____

9.2 Please indicate in the boxes below the number of oocytes and embryos received and the number that were used in all your currently licensed research projects. This allows audit of embryos received but found to be unsuitable for research. Please give the name(s) of the centre(s) which supplied the material and give the data for each supplying centre separately.
請於下列方格填寫中心就各項現已領有牌照的研究項目分別接獲及使用的卵母細胞及胚胎數量，以便審查已接獲但後來發現不宜用於研究的胚胎數量。請填寫供應有關物料的中心的名稱，並列出每一供應中心分別提供的物料的數量。

Dates From To
日期： 由： 至：
Centre Name
供應中心名稱：

Total no. of embryos received **所接獲胚胎的總數**	**Total no. of embryos used** **所使用胚胎的總數**	**Total no. of oocytes received** **所接獲卵母細胞的總數**	**Total no. of oocytes used** **所使用卵母細胞的總數**
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

Dates From To
日期： 由： 至：
Centre Name
供應中心名稱：

Total no. of embryos received **所接獲胚胎的總數**	**Total no. of embryos used** **所使用胚胎的總數**	**Total no. of oocytes received** **所接獲卵母細胞的總數**	**Total no. of oocytes used** **所使用卵母細胞的總數**
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Abstract 摘要

10.1 Please give a summary of the work you propose to undertake (maximum of 200 words).
請概述擬進行的研究工作(以 200 字為限)。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

11. Objectives 目標

11.1 Please state the aims and objectives of the project.
請說明擬領牌的研究項目的目的及目標。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

12. Background 背景

12.1 Please state how the project fits into the current state of knowledge on this subject (maximum of 1,500 words).
請說明擬領牌的研究項目如何切合有關學科的現有知識範疇(以 1,500 字為限)。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

13. Methodology/Experimental Design/Analysis of Results 方法/實驗設計/結果分析

13.1 Please state how this work is to be carried out.
請說明如何進行研究工作。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

14. Staff 職員

14.1 Please list all the staff who will be involved in the proposed research.
請列明將會參與擬領牌的研究項目的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……

15. Institutional Research Ethics Committee 機構的科技研究倫理委員會

15.1 Please state the role of the research ethics committee.
請說明科技研究倫理委員會的角色。

15.2 Please list the chairperson and membership of the research ethics committee.
請列明科技研究倫理委員會的主席和成員及其相關資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
Chairman 主席		
……	……	……
Membership 成員		
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

15.3 Details of the approval of the research ethics committee on the research project under licence application.
科技研究倫理委員會審批擬領牌的研究項目的詳情。

16. Funding 撥款

16.1 Please supply copies of the sections on the objectives and protocols in any funding application made, excluding financial details.
如曾就擬領牌的研究項目申請撥款，請提供撥款申請書中有關目標及方案部分的副本(財務詳情除外)。

17. Supporting Documentation 證明文件

17.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

Appendix A:	CVs (see Annex 10 of the "Licensing Manual for Reproductive Technology Centres") of all staff engaged directly in the research project Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
Appendix B:	Relevant clinical and laboratory protocols, and protocol for the research
Appendix C:	Consent forms regarding use of oocytes/embryos for this project
Appendix D:	Contingency plan to be adopted by the centre
Appendix E:	Up to three most recent relevant publications (if any)
附錄 A：	所有直接參與研究項目的職員的履歷表(《供生殖科技中心參考的發牌手冊》附件 10) 請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。
附錄 B：	與擬領牌的研究項目相關的臨牀、化驗室及研究方案
附錄 C：	關於擬領牌的研究項目使用卵母細胞/胚胎的同意書
附錄 D：	中心所用的應變計劃
附錄 E：	最近發表的資料(如有，請提供最多三份資料)

18. Declarations 聲明

18.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

18.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

18.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同負責人向管理局提交一份研究結果報告。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

18.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同持牌人向管理局提交一份研究結果報告。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Research Licence Application Form
研究牌照申請書填寫須知
(First-time Application)
(首次申請)

General Information 一般資料

1. The Human Reproductive Technology Ordinance (Cap. 561) requires centres undertaking embryo research to first obtain a licence from the Council on Human Reproductive Technology. The Council puts strict limitations on the type of research permitted. 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 –
《人類生殖科技條例》(第 561 章) 訂明，進行胚胎研究必須先向人類生殖科技管理局申領牌照。管理局對獲准進行的研究種類嚴加限制。在一般情況下，管理局不會發出牌照，除非管理局認為該項目對促進以下一個或多個目的屬必需或合宜：
   a. to promote advances in the treatment of infertility;
   促進不育治療的發展；
   b. to increase knowledge about the causes or treatment of congenital disease;
   增進有關先天性疾病的成因或治療方面的知識；
   c. to increase knowledge about the causes or treatment of miscarriages;
   增進有關流產問題的成因或治療方面的知識；
   d. to develop more effective techniques of contraception;
   發展更有效的避孕方法；
   e. to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;
   發展技術，在胚胎植入母體前，偵察胚胎內基因或染色體的異常情況；
   f. to increase knowledge about the development of embryos;
   增進有關胚胎發展的知識；
   g. to increase knowledge about serious diseases; and
   增進有關嚴重疾病的知識；及
   h. to enable such knowledge to be applied in the development of treatments to combat serious diseases. *(Paragraph 11.5 of the Code)*
   致使所得知識用於發展相關治療方法，以對抗嚴重疾病。*(《實務守則》第 11.5 段)*

2. The proposed project must be considered to be scientifically valid by the Council. Otherwise, it will not be approved.
擬領牌的研究項目必須是管理局認為是具有充分科學根據的，否則不會獲得批准。

3. The following activities are prohibited by law :
香港法例禁止以下活動：

   a. keeping or using an embryo after the appearance of the primitive streak. For this purpose, the primitive streak shall be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored;
   保留或使用已出現原痕的胚胎。就此而言，原痕須視為在自配子混合當日起計的14日期間屆滿時或之前已在胚胎內出現，而該胚胎儲存時的任何時間則不計算在內；
   b. bringing about the creation of an embryo for the purposes of embryo research;
   為胚胎研究的目的，促成胚胎的製造；
   c. combining human and non-human gametes / embryo or any part thereof such as to give rise to a 2 cell zygote for the purposes of embryo research;
   為胚胎研究的目的，將人類及非人類配子或胚胎或其任何部分結合，以形成雙細胞合子；
   d. placing any non-human gametes or embryo or any part thereof in any human;
   將非人類配子或胚胎或其任何部分放置於人體內；

e. placing any human gametes or embryo or any part thereof in any animal;
將人類配子或胚胎或其任何部分放置於動物體內；

f. replacing the nucleus of a cell of an embryo with a nucleus taken from any other cell;
將胚胎的細胞核以取自其他細胞的細胞核取代；及

g. cloning any embryo.
將胚胎進行無性繁殖。

(Section 15(1) of the Ordinance)
(《條例》第15(1)條)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 6
第 6 部分:
Give a realistic timescale for the duration of the study. Please note that under section 25(a)(i) of the Human Reproductive Technology Ordinance (Cap. 561), the maximum duration for a licence is 3 years.
此部分須為擬領牌的研究項目提供切合實際的期限。請注意，根據《人類生殖科技條例》(第 561 章) 第 25(a)(i)條，牌照期以三年為限。

Section 10
第 10 部分:
The Council has a responsibility to inform the public of the research work it has licensed. Please summarize in non-technical/lay language the aims and designs of your work (maximum of 200 words).
管理局有責任把獲發牌照的研究工作告知公眾。請以淺白易明的文字概述研究工作的目的及設計(以 200 字為限)。

Section 11
第 11 部分:
State clearly and briefly the scientific objectives of the research and how any knowledge gained will help to achieve the purposes of research under the Code.
此部分須清楚扼要地說明擬領牌的研究項目的科學目標，以及所得知識如何有助達到《實務守則》所訂明的研究目的。

Section 12
第 12 部分:
Explain how the proposed research fits into the current state of knowledge on the subject and make clear what your own contribution to this has been. Indicate how work on model systems is irrelevant or has been exhausted and therefore the use of human embryos is justifiable (maximum of 1,500 words).
此部分須闡釋擬領牌的研究項目如何切合有關學科的現有知識範疇，並清楚說明中心在這方面所作出的貢獻。請說明為何利用模擬系統的方法並不相關或已經用盡，以致有充分理由支持要用人類胚胎進行研究(以 1,500 字為限)。

Section 13
第 13 部分:
Show how the work is to be carried out indicating -

- experimental design;
- techniques to be used;
- measurements to be made;
- statistical methods to be used for analysis of results.

此部分須就下列各項闡明研究工作如何進行：

- 實驗設計；
- 將會採用的技術；
- 將會進行的測量工作；
- 將會用作分析結果的統計方法。

Section 14
第 14 部分:
All staff who will be directly involved in the research project should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與擬領牌的研究項目的全部職員及其所任職位。

Section 15
第 15 部分:
Centres should provide a full list of all members of the research ethics committee which oversees their work, including any qualifications and experiences which are relevant to their membership of the committee.
此部分須列明負責監管中心工作的科技研究倫理委員會的全部成員，包括各成員所具備與其委員會工作相關的資格及經驗。

Section 18
第 18 部分:
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 6

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

APPLICATION FOR RESEARCH LICENCE (RENEWAL)
研究牌照申請書 (續期申請)

Name of Centre in English: ……...
中心名稱 (英文)：

Name of Centre in Chinese: ……..….
中心名稱 (中文)：

Licence Number: …….
牌照號碼：

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

Title of Project 項目名稱： ……..……....….
……..……....….
……..…….
……..…….

The completed form should be returned together with supporting documentation and the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form.
* 本申請書末頁載有填寫須知，可供參考。

1. Details of the Centre Undertaking Research 進行研究的中心的資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the embryo research project is intended to be carried out belong to the following class (please tick the appropriate box):
擬進行有關胚胎研究項目的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格內加上✓號。)

Hospital Authority facility 醫院管理局轄下設施 ☐ **Private** 私營機構 ☐ **Other institutions** 其他機構 ☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Title of Research Project 研究項目的名稱

5.1 Please give the full title of the project.
請提供擬續牌的研究項目的全稱。

_____

_____

_____

_____

_____

_____

5.2 Has the title of the project changed since the previous licence was granted? (Please tick the appropriate box)
自上次獲發牌照後，項目名稱有沒有改動？(請在適當方格加上✓號。)

Yes 有 ☐ **No 沒有** ☐

6. Expiry of Current Licence 現有牌照的屆滿日期

6.1 Please give the date your current licence expires.
請提供現有牌照的屆滿日期。

_____

7. Duration of Project 研究項目的期限

7.1 Please indicate the period of time for which you wish the renewal licence to be granted (not more than 3 years).
請說明希望獲批的牌照有效期(不超過 3 年)。

8. Receipt and Usage of Material 所接獲及使用的物料

8.1 Please indicate in the boxes below the number of oocytes and embryos received and the number that were used during the period of the current licence, in the research project for which you are applying. This allows audit of embryos allocated to research, including those found to be unsuitable for research. Please give the name(s) of the centre(s) which supplied the material and give the data for each supplying centre separately.
請於下列方格填寫現有牌照的有效期內中心就擬續牌的研究項目所接獲及使用的卵母細胞及胚胎數量，以便審查該項目所獲分配的胚胎數目，包括其後發現不宜用於研究的胚胎數目。請填寫供應有關物料的中心的名稱，並就每一供應中心提供相關資料。

Dates From 日期： 由： _____ To 至： _____
Centre Name 供應中心名稱： _____

Total no. of embryos received 所接獲的胚胎總數	**Total no. of embryos used 所使用的胚胎總數**	**Total no. of oocytes received 所接獲的卵母細胞總數**	**Total no. of oocytes used 所使用的卵母細胞總數**
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

Dates From 日期： 由： _____ To 至： _____
Centre Name 供應中心名稱： _____

Total no. of embryos received 所接獲的胚胎總數	**Total no. of embryos used 所使用的胚胎總數**	**Total no. of oocytes received 所接獲的卵母細胞總數**	**Total no. of oocytes used 所使用的卵母細胞總數**
Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：	Fresh 新鮮：
Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：	Frozen 冷藏：
		Failed to Fertilize 不能受精：	Failed to Fertilize 不能受精：

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

8.2 Have any of the above embryos been used in licensed research projects at other centres? If so, please list the research project numbers and the number of embryos concerned.
上述胚胎曾否用於其他中心領有牌照的研究項目？如有，請列出有關研究項目的編號及所涉胚胎的數量。

8.3 If the numbers recorded in 8.1 above differ substantially from those estimated in the original proposal, please give the reasons below.
如上文 8.1 段所述數量與原來建議書的預計數量差別甚大，請在下面說明原因。

9. Estimated Use of Material During Renewal Period 續期牌照有效期內預計使用物料的數量

9.1 Please indicate in the boxes below the estimated numbers of oocytes and embryos you expect to use during the renewal period applied. If more than one year has been requested please indicate the yearly usage in the appropriate boxes.
請於下列方格填寫預計會於續期牌照有效期內使用的卵母細胞及胚胎數量。如為牌照申請續期超過一年，請在適當方格填上每年的使用數量。

Material 物料	**Year 1 第一年**	**Year 2 第二年**	**Year 3 第三年**
Fresh Oocytes* 新鮮卵母細胞*			
Frozen Oocytes 冷藏卵母細胞			
Failed to fertilize Oocytes 不能受精的卵母細胞			
Fresh Embryos 新鮮胚胎			
Frozen Embryos 冷藏胚胎			

(*If immature oocytes will be used, please indicate.) (*如將使用未成熟的卵母細胞，請加以註明。)

10. Progress Report on Work Undertaken During Period of Previous Licence
上次牌照有效期內所進行的工作的進度報告

10.1 Please give a report below in scientific terms specifying clearly how the actual outcome of the research relates to its stated objectives, under the following headings:
請於下面以科學用語作出匯報，以清楚說明研究的實際結果與所訂目標有何關係，請按以下標題提供資料：

(a) how the work undertaken relates to the objectives and purposes of your previous application;
所進行的工作與先前申請書所載的目標及目的有何關係；
(b) research undertaken to date;
至今已進行的研究；
(c) results;
結果；
(d) if progress was slower than anticipated, the reasons for this;
進度如較預期慢，原因何在；
(e) if work originally proposed was not carried out, again, the reasons for this.
如原擬進行的工作並無落實，原因何在。

Please continue on a separate sheet. 如有需要，請另頁續寫。

11. Future Work 未來工作

11.1 Please summarize below the work that you propose to carry out during the period for which you are applying to be licensed and how it relates to the results of the work undertaken on the previous licence. Please use the following headings:
請於下面概述擬於續期牌照有效期內所進行的工作，以及該等工作與上一牌照所得研究結果有何關係。請按以下標題提供資料：

(a) renewed objectives;
更新後的目標；
(b) methods;
方法；
(c) discussion (with particular reference to how the proposed studies relate to the objectives outlined in the licence application and to the findings to date as outlined in Section 10 above).
討論(重點說明建議研究與本續期申請書所述的目標有何關係，以及與上文第10部分所述至今所得研究結果有何關係)。

Please continue on a separate sheet. 如有需要，請另頁續寫。

12. Publications 發表

12.1 Please list below any publications which have resulted from this work.
請在下面列出曾就有關研究工作所發表的資料。

13. Staff 職員

13.1 Please list any staff changes that have taken place.
請列出任何人事變動的資料。

Staff who have joined 新加入的職員

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….

Staff who have left 已離職的職員

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….

14. Institutional Research Ethics Committee 機構的科技研究倫理委員會

14.1 Please provide a current list of the membership of the research ethics committee.
請列出科技研究倫理委員會的現任主席及現有成員。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
Chairman 主席		
……..	…….	…….
Membership 成員		
……..	…….	…….
……..	…….	…….
……..	…….	…….
……..	…….	…….
……..	…….	…….
……..	…….	…….
……..	…….	…….
……..	…….	…….

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

15. Funding 撥款

15.1 Please supply copies of the sections on the objectives and protocols in any funding application made, excluding financial details.
如曾就擬續牌項目申請撥款，請提供撥款申請書中有關目標及方案部分的副本(財務詳情除外)。

16. Supporting Documentation 證明文件

16.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

Appendix A: CVs (see Annex 10 of the "Licensing Manual for Reproductive Technology Centres") of any new staff engaged directly in the research project
Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.

Appendix B: Any new clinical or laboratory protocols that may be relevant

Appendix C: Any new consent forms

Appendix D: Contingency plan (if revised)

Appendix E: Any publications resulting from this project

附錄 A： 任何直接參與研究計劃的新職員的履歷表(《供生殖科技中心參考的發牌手冊》附件 10)
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

附錄 B： 任何可能有關的新增臨牀或化驗室方案

附錄 C： 任何新增的同意書

附錄 D： 應變計劃(如曾修訂)

附錄 E： 曾就擬續牌研究項目所發表的資料

17. Declarations 聲明

17.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

17.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

17.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同負責人向管理局提交一份研究結果報告。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

17.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I accept that should the application be approved for licensing, I will be required to jointly submit a report of the findings to the Council when the research is completed. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄提供的資料真確無誤。本人接受，牌照申請如獲批准，本人須於研究完成後聯同持牌人向管理局提交一份研究結果報告。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Research Licence Application Form
研究牌照申請書填寫須知
(Renewal Application)
(續期申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 7
第 7 部分：
Give a realistic timescale for the duration of the study. Please note that under section 25(a)(i) of the Human Reproductive Technology Ordinance (Cap. 561), the maximum duration for a licence is 3 years.
此部分須就擬續牌項目提供切合實際的期限。請注意，根據《人類生殖科技條例》(第 561 章) 第 25(a)(i)條，牌照期以三年為限。

Section 13
第 13 部分：
Any changes on staff who is directly involved in the research project should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與擬續牌項目的職員的任何變動，包括有關職員的姓名及職位。

Section 14
第 14 部分：
Centres should provide a full list of all members of the research ethics committee which oversees their work, including any qualifications and experiences which are relevant to their membership of the committee.
此部分須列明負責監管中心工作的科技研究倫理委員會的全部成員，包括各成員所具備與其委員會工作相關的資格及經驗。

Section 17
第 17 部分：
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 7

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

APPLICATION FOR LICENCE TO STORE GAMETES, EMBRYOS AND/OR TESTICULAR/OVARIAN TISSUE (FIRST-TIME APPLICATION)
配子、胚胎及/或睪丸/卵巢組織儲存牌照申請書 (首次申請)

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese:..……..……
中心名稱 (中文)：

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

The completed form should be returned together with supporting documentation and the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

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

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form. The name of licence applicant, the address of the premises where relevant activities are intended to be carried out and the class of licence applied for will be published in the website of the Council on Human Reproductive Technology for public access.
* 本申請書末頁載有填寫須知，可供參考。公眾人士可在人類生殖科技管理局網頁內查閱牌照申請人的姓名/名稱，擬進行有關活動的處所地址及所申請的牌照類別。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the storage of gametes, embryos and/or testicular/ovarian tissue is intended to be carried out belong to the following class (please tick the appropriate box):
擬儲存配子、胚胎及/或睪丸/卵巢組織的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號。)

Hospital Authority facility 醫院管理局轄下設施 ☐ **Private** 私營機構 ☐ **Other institutions** 其他機構 ☐

2.2 If private, please provide the following information as appropriate:
如為私營機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Materials to be Stored 擬儲存的物料

5.1 Please tick the appropriate boxes below to indicate the material(s) the centre wishes to be licensed to store :
請在下列適當方格加上✓號，以說明中心擬領牌儲存的物料：

Material 物料	*To be licensed to store 擬領牌儲存的物料*
Semen/ Sperm (donor/ patient*) 精液/精子(捐贈人/病人*)	
Oocyte (donor/ patient*) 卵母細胞(捐贈人/病人*)	
Embryo (donor/ patient*) 胚胎(捐贈人/病人*)	
Testicular tissue# 睪丸組織 #	
Ovarian tissue# 卵巢組織 #	

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

Storage of testicular and ovarian tissue will require a licence only if gametes are present in the tissue. The Council works according to the following definition of gametes: "Gametes refer to 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".

儲存含有配子的睪丸和卵巢組織必須領牌。管理局行事時所依據的配子定義為：「配子指生殖細胞，即男性的精子和女性的卵子；精子及卵子融合後便形成合子。每個人類配子包含內有 23 個染色體的基本組合(單倍體的組合)。卵子與精子融合時，便成為內有 46 個染色體的完整組合(雙倍體組合)。其他所有軀體細胞的細胞核，均含有 46 個染色體。」

6. Reasons for Storage 儲存原因

6.1 Please indicate the various groups for whom storage facilities will be made available e.g. oncology patients.
請說明擬向其提供儲存設施的服務對象，例如腫瘤科病人等。

_____

_____

_____

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7. Staff 職員

7.1 Please list the staff of the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed in this section.
請列出中心內擔任下列職位的職員，並就下表所列全部職員提交履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	Proposed Licensee 準持牌人	See CV 見履歷表
…….	Proposed Person Responsible 準負責人	See CV 見履歷表
…….	Embryologist in charge 主任胚胎學家	See CV 見履歷表
…….	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
…….	Counsellor in charge 主任輔導員	See CV 見履歷表

7.2 Please list below all staff members of the centre involved in the storage of gametes, embryos and/or testicular/ovarian tissue or who have access to client/patient records.
請列出中心內參與配子、胚胎及/或睪丸/卵巢組織儲存工作或會接觸當事人/病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……
……	……	……
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Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.3 Please provide the details of the centre's complaint officer.
請提供中心內投訴主任的資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
……	……	……

8. Supporting Documentation 證明文件

8.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

8.2 CVs for each of the staff listed in paragraph 7.1 (marked collectively as Appendix A). They may include:
第 7.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Embryologist in charge 主任胚胎學家
(d) Nurse Co-ordinator 護士統籌主任
(e) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

8.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

8.4 One complete set of all consent forms to be used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

8.5 One complete set of all storage forms to be used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部儲存表格的整套資料一份，包括問卷(一律標明為附錄 D)。

8.6 One complete set of all standard operating procedures and protocols to be used by the centre, including procedures and protocols appertaining to assessment of clients/patients/donors, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與當事人/病人/捐贈人評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

8.7 One copy of contingency plan to be adopted by the centre (marked as Appendix F).
中心所用應變計劃的複本一份(標明為附錄 F)。

9. Additional Information 其他資料

9.1 Is there any other information regarding your centre which you may wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed on this form?
是否還有其他與中心和本申請有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

_____
_____
_____
_____
_____
_____

9.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

_____
_____
_____
_____
_____
_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Declarations 聲明

10.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

10.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

10.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

10.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Storage Licence Application Form
儲存牌照申請書填寫須知
(First-time Application)
(首次申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》

Section 5
第 5 部分：
Storage of gametes, embryos and/or testicular/ovarian tissue is a relevant activity governed by the Human Reproductive Technology Ordinance (Cap. 561). Centre must indicate the material(s) for which it wishes to be licensed to store.
儲存配子、胚胎及/或睾丸/卵巢組織是《人類生殖科技條例》(第 561 章) 所規管的有關活動。中心必須列明擬領牌儲存的物料。

Section 7
第 7 部分：
All staff who will be directly involved in the storage of gametes, embryos and/or testicular/ovarian tissue or who have access to client/patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與配子、胚胎及/或睪丸/卵巢組織儲存工作或會接觸當事人/病人記錄的全部職員及其職位。

Section 10
第 10 部分：
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 8

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

APPLICATION FOR LICENCE TO STORE GAMETES, EMBRYOS AND/OR TESTICULAR/OVARIAN TISSUE (RENEWAL)
配子、胚胎及/或睪丸/卵巢組織儲存牌照申請書（續期申請）

Name of Centre in English: ……
中心名稱 (英文)：

Name of Centre in Chinese: ……
中心名稱 (中文)：

Licence Number: …….
牌照號碼：

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

The completed form should be returned together with supporting documentation and the application fee of HK$1,200 to:
填妥的申請書須連同證明文件及申請費用港幣 1,200 元交回：

Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai
Hong Kong
香港灣仔
皇后大道東 213 號
胡忠大廈 17 樓 58 號室
人類生殖科技管理局

Payment of application fee should be made by a crossed cheque (made payable to "The Government of the Hong Kong Special Administrative Region" or "The Government of the HKSAR"), with the name of the centre written at the back of the cheque. Please do not send cash by post.
申請費用須以劃線支票支付，收款人註明「香港特別行政區政府」，並請在支票背面寫上中心名稱，請勿郵寄現金。

* For guidance on how to fill in this application form, please refer to the Guidance Notes which are at the end of this form.
* 本申請書末頁載有填寫須知，可供參考。

1. Details of Centre 中心資料

1.1 Name of centre/institution (including department) 中心/機構名稱(包括部門名稱)：

_____

1.2 Address 地址：

_____

_____

_____

_____

Correspondence address (if different):
通訊地址(如與左列資料不同)：

_____

_____

_____

_____

1.3 Tel No. 電話號碼：_____ Tel No. 電話號碼：_____

1.4 Fax No. 傳真號碼：_____ Fax No. 傳真號碼：_____

1.5 E-mail address (if applicable):
電郵地址(如適用)：_____

1.6 Website address (if applicable):
網址(如適用)：_____

1.7 The premises where the storage of gametes, embryos and/or testicular/ovarian tissue is intended to be carried out belong to the following class (please tick the appropriate box):
擬儲存配子、胚胎及/或睾丸/卵巢組織的處所屬以下類別(請在適當方格加上✓號):

(a) a clinic registered under the Medical Clinics Ordinance (Cap. 343)
根據《診療所條例》(第 343 章)註冊的診療所 ☐

(b) a hospital or maternity home registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)
根據《醫院、護養院及留產院註冊條例》(第 165 章)註冊的醫院或留產院 ☐

(c) a public hospital as defined under section 2(1) of the Hospital Authority Ordinance (Cap. 113)
《醫院管理局條例》(第 113 章)第 2(1)條界定的公營醫院 ☐

(d) a private consulting room that is :
(i) used by a registered medical practitioner in the course of his practice; and
(ii) not located in premises used for residential purposes ☐
符合以下說明的私人診症室：
(i) 是由註冊醫生在其執業過程中所使用；及
(ii) 並非位於作住宅用途的處所

(e) a medical or research laboratory that is not located in premises used for residential purposes ☐
並非位於作住宅用途的處所的醫務或研究實驗室

2. Corporate Information 機構資料

2.1 Is the centre a Hospital Authority facility and/or a private operation? (Please tick the appropriate box)
中心是否醫院管理局轄下設施及/或私營機構？(請在適當方格加上✓號)

Hospital Authority facility 醫院管理局轄下設施	☐	**Private** 私營機構	☐	**Other institutions** 其他機構	☐

2.2 If private, please provide the following information as appropriate:
如為私人機構，請在下面提供適當資料：

i) Limited Company 有限公司：

Company Name 公司名稱：

Registration No. 註冊編號：

Registered Offices 註冊辦事處：

ii) Partnership 合夥經營：

Particulars of Partners 合夥人資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

iii) Sole Proprietor 獨資經營：

Particulars of Owner 東主資料：

Name 姓名：

HKID Card / Passport No. :
香港身分證/護照號碼：

Correspondence address:
通訊地址：

Tel No. 電話號碼：

Fax No. 傳真號碼：

E-mail address (if applicable):
電郵地址(如適用)：

2.3 Has the ownership (or the **controlling interest**) of the centre changed in the past year? (Please tick the appropriate box)
中心的擁有權(或**控制權益**)在過去一年有沒有改變？(請在適當方格加上✓號)

Yes 有 ☐ **No** 沒有 ☐

If yes, please give details below 如有，請在下面詳加說明：

_____

_____

_____

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

3. Details of Applicant 申請人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

4. Details of Proposed Person Responsible 準負責人資料

Name 姓名： _____ English 英文 _____ Chinese 中文

Position 職位： _____

_____

HKID Card / Passport No. : 香港身分證/護照號碼： _____

5. Materials to be Stored 所儲存的物料

5.1 Please state the date licensed storage was first offered at this centre:
請列出中心首次提供領牌儲存服務的日期：

_____

5.2 Please tick the appropriate boxes below to indicate the material(s) which the centre is currently licensed to store plus those materials which the centre wishes to include in the renewal licence:
請在適當方格加上✓號，以說明中心現已領牌儲存及現擬納入續期牌照的物料：

Material *物料*	*Currently licensed* *現已領牌儲存的物料*	*To be included in renewal licence (including currently licensed)* *現擬納入續期牌照物料* *(包括現已領牌儲存的物料)*
Semen/ Sperm (donor/ patient*) 精液/精子(捐贈人/病人*)		
Oocyte (donor/ patient*) 卵母細胞(捐贈人/病人*)		
Embryo (donor/ patient*) 胚胎(捐贈人/病人*)		
Testicular tissue# 睪丸組織 #		
Ovarian tissue# 卵巢組織#		

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

6. **Reasons for Storage 儲存原因**

6.1 Please indicate the various groups for whom storage facilities will be made available e.g. oncology patients.
請說明擬向其提供儲存設施的服務對象，例如腫瘤科病人等。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

Storage of testicular and ovarian tissue will require a licence only if gametes are present in the tissue. The Council works according to the following definition of gametes: "Gametes refer to 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".

儲存含有配子的睪丸和卵巢組織必須領牌。管理局行事時所依據的配子定義為：「配子指生殖細胞，即男性的精子和女性的卵子；精子及卵子融合後便形成合子。每個人類配子包含內有 23 個染色體的基本組合(單倍體的組合)。卵子與精子融合時，便成為內有 46 個染色體的完整組合(雙倍體組合)。其他所有軀體細胞的細胞核，均含有 46 個染色體。」

7. Staff 職員

7.1 Please list the staff at the centre occupying the following roles. A CV (at Annex 10 of the "Licensing Manual for Reproductive Technology Centres") must be provided for all staff listed in this section.
請列出中心內擔任下列職位的職員，並就下表所列全部職員提交履歷表(《供生殖科技中心參考的發牌手冊》附件 10)。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	Proposed Licensee 準持牌人	See CV 見履歷表
…….	Proposed Person Responsible 準負責人	See CV 見履歷表
…….	Embryologist in charge 主任胚胎學家	See CV 見履歷表
…….	Nurse Co-ordinator 護士統籌主任	See CV 見履歷表
…….	Counsellor in charge 主任輔導員	See CV 見履歷表

7.2 Please list below all staff members in the centre involved in the storage of gametes, embryos and/or testicular/ovarian tissue or who have access to client/patient records.
請列出中心內參與配子、胚胎及/或睪丸/卵巢組織儲存工作或會接觸當事人/病人記錄的全部職員及其相關資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….
…….	…….	…….

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

7.3 Please provide the details of the centre's complaint officer.
請提供中心內投訴主任的資料。

Name *姓名*	*Profession/Position* *專業/職位*	*Qualification/Experience* *資格/經驗*
…….	……	…….

8. Supporting Documentation 證明文件

8.1 In order to process this application it is essential that the Council is provided with a full set of the appropriate supporting documentation. Documents to be included as part of this application are listed below. Each set of documents should be labeled as an Appendix (using the appropriate designation as indicated below).
請提交所有證明文件以便管理局處理本申請。下文臚列須附於申請書的各類文件。請為每套文件標明附錄編號(按照下文所示的適當編號)。

8.2 CVs for each of the staff listed in paragraph 7.1 (marked collectively as Appendix A). They may include:
第 7.1 段所列每位職員的履歷表(一律標明為附錄 A)，當中可包括：

(a) Proposed Licensee 準持牌人
(b) Proposed Person(s) Responsible 準負責人
(c) Embryologist in charge 主任胚胎學家
(d) Nurse Co-ordinator 護士統籌主任
(e) Counsellor in charge 主任輔導員

No CVs other than those mentioned above should be submitted. All CVs should be submitted using the Council's standard form supplied.
並非上述職員的履歷表無須提交。全部履歷表須採用管理局所提供的標準表格。

Please provide a photocopy of the HKID Card/ Passport of the proposed licensee (applicable to application by individual) and the proposed person(s) responsible.
請提供準持牌人(適用於以個人名義提出的申請)及準負責人的香港身分證/護照影印本。

8.3 One copy of all information leaflets/booklets, price list, newsletters, etc. (marked collectively as Appendix B). If booklets are published, please submit 5 copies.
資料單張/小冊子、收費表及通訊等整套資料一份(一律標明為附錄 B)。如有印刷小冊子，請提交五份。

8.4 One complete set of all consent forms used by the centre (marked collectively as Appendix C).
中心所用全部同意書的整套資料一份(一律標明為附錄 C)。

8.5 One complete set of all storage forms used by the centre, including questionnaires (marked collectively as Appendix D).
中心所用全部儲存表格的整套資料一份，包括問卷(一律標明為附錄 D)。

8.6 One complete set of all standard operating procedures and protocols used by the centre, including procedures and protocols appertaining to assessment of clients/patients/donors, handling of complaints, and counselling, as well as clinical and laboratory procedures (marked collectively as Appendix E).
中心所用標準運作程序和方案的整套文件一份，包括與當事人/病人/捐贈人評估、投訴處理及輔導有關的程序和方案，以及臨牀和化驗程序(一律標明為附錄 E)。

8.7 One copy of contingency plan to be adopted by the centre (marked as Appendix F).
中心所用應變計劃的複本一份(標明為附錄 F)。

9. Special Conditions 特別條件

9.1 Details of the action taken to address any special conditions specified by the Council, applicable to the current licence, should be given below.
中心因應管理局所指明並適用於現行牌照的任何特別條件而採取的行動，請在下面詳加說明。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

10. Additional Information 其他資料

10.1 Is there any other information regarding your centre which you wish to bring to the attention of the Council, which is pertinent to this application, and which has not yet been addressed on this form? If so, please give details below.
是否還有其他與中心有關但未在申請書內提及而又希望管理局知悉的資料？如有，請在下面詳加說明。

10.2 Please outline below any plans for the coming year which you wish to bring to the attention of the Council.
如有任何希望管理局知悉的來年計劃，請在此處概述。

Please continue on a separate sheet if required. 如有需要，請另頁續寫。

11. Declarations 聲明

11.1 Persons signing this application form should note that section 27 of the Human Reproductive Technology Ordinance (Cap. 561) provides that the Council may revoke a licence if it is satisfied that any information given in the application for the grant of the licence was in any material respect false or misleading. They should also note that under section 39(2) of the Ordinance, the provision of false or misleading information knowingly or recklessly for the purposes of the grant of a licence is a criminal offence.
簽署本申請書的人士請注意，《人類生殖科技條例》(第 561 章) 第 27 條訂明，管理局如信納在要求發給該牌照的申請中提供的資料在要項上屬虛假或具誤導性，則可撤銷牌照。簽署人另須注意，根據該條例第 39(2)條，任何人為牌照的發給的目的，明知或罔顧後果地提供在要項上屬虛假或具誤導性的任何資料，即屬犯罪。

11.2 Where a change in any information provided in relation to an application for a licence occurs before the determination of the application, the applicant shall give notice of the change to the Council within 28 days after its occurrence unless the application has been withdrawn.
除申請已被撤回的情況外，如有關牌照申請所提供的資料在管理局作出決定前有任何變更，申請人必須在有關變更的 28 天內向管理局呈報。

Applicant 申請人

11.3 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the licensee.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任持牌人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

Proposed Person Responsible 準負責人

11.4 The information provided in this form and its appendices is to the best of my knowledge, information and belief true and accurate. I agree to act as the person responsible.
盡本人所知、所得資料及所信，本申請書及其附錄所提供的資料真確無誤。本人同意擔任負責人。

Signature 簽署_____ Name 姓名_____ Date 日期_____

- END 完-

Guidance Notes on Completing Storage Licence Application Form
儲存牌照申請書填寫須知
(Renewal Application)
(續期申請)

Section 3
第 3 部分：
The applicant is the person who will hold the licence. The applicant shall secure that the person responsible under the licence discharges his duties.
申請人即將會持有牌照的人士。申請人須確保牌照負責人履行有關責任。

Section 4
第 4 部分：
The proposed person responsible is the person under whose supervision the activities authorized by a licence will be carried out. The person should have the following qualifications:

(a) a registered medical practitioner;
(b) a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) 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.

The person responsible will have certain statutory duties as set out in section 24 of the Human Reproductive Technology Ordinance (Cap. 561). Further details are given in the Code.

準負責人即須在其監管下進行牌照所授權活動的人士。該人須具備下列資格:

(a) 註冊醫生；
(b) 《護士註冊條例》(第164章)所指的註冊護士；
(c) 根據《醫務化驗師(註冊及紀律處分程序)規例》(第359章，附屬法例A)註冊的醫務化驗師；
(d) 管理局認為攸關人類生殖科技的科學範疇的學士學位或學士以上程度學位；或
(e) 管理局認為為監管該申請書所指明的有關活動的目的屬可予接受的醫學、護理學、科學或管理學範疇的其他資格。

負責人須承擔《人類生殖科技條例》(第 561 章) 第 24 條所訂明的相關法定責任。其他詳情載於《實務守則》。

Section 5
第 5 部分：
Storage of gametes, embryos and/or testicular/ovarian tissue is a relevant activity governed by the Human Reproductive Technology Ordinance (Cap. 561). Centre must indicate those material(s) for which it wishes to renew its licence for storage plus those it wishes to include in the new licence.
儲存配子、胚胎及/或睪丸/卵巢組織是《人類生殖科技條例》(第 561 章) 所規管的有關活動。中心必須列明擬續牌及擬納入新牌照的物料。

Section 7
第 7 部分：
All staff who will be directly involved in the storage of gametes, embryos and/or testicular/ovarian tissue or who have access to client/patient records should be listed here along with the position each holds in the centre.
此部分須列明中心內直接參與配子、胚胎及/或睪丸/卵巢組織儲存工作或會接觸當事人/病人記錄的全部職員及其職位。

Section 11
第 11 部分：
When signing the declarations section, it should be noted that if the proposed person responsible is also the applicant, he or she should sign both sections.
在簽署聲明時，請注意準負責人如同時亦是申請人，則應簽署聲明中兩個相關部分。

Annex 9

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

APPLICATION FOR PGD WITH TISSUE TYPING
植入前基因診斷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 Diagnosis (PGD) 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 PGD 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「植入前基因診斷倫理指引」進行植入前基因診斷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 PGD issued by the HRT Council?
是否已根據管理局所發出的「植入前基因診斷倫理指引」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 PGD 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「植入前基因診斷倫理指引」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.