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.

---

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)*

---

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.

---

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.

---

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)*