

HUMAN REPRODUCTIVE TECHNOLOGY ORDINANCE

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HONG KONG SPECIAL ADMINISTRATIVE REGION

ORDINANCE NO. 47 OF 2000

L.S.

TUNG Chee-hwa
Chief Executive
29 June 2000

An Ordinance to regulate reproductive technology procedures, and the use, for research and other purposes, of embryos and gametes; to confine the provision of reproductive technology procedures to infertile couples subject to any express provision to the contrary in any code; to regulate surrogacy arrangements; to establish a Council on Human Reproductive Technology; and to provide for matters incidental thereto or connected therewith.

[]

Enacted by the Legislative Council.

PART I

PRELIMINARY

1. Short title and commencement

(1) This Ordinance may be cited as the Human Reproductive Technology Ordinance.

(2) This Ordinance shall come into operation on a day to be appointed by the Secretary for Health and Welfare by notice in the Gazette.

2. Interpretation

(1) In this Ordinance, unless the context otherwise requires—
“advertisement” (廣告) includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;

- “artificial insemination” (人工授精) means a procedure under which sperm are introduced into the vagina or uterus of a woman otherwise than by sexual intercourse;
- “authorized person” (獲授權人士) means—
- (a) a member of the Council or of a committee; or
 - (b) a designated public officer;
- “code” (守則) means a code of practice prepared and maintained under section 8, as in force from time to time;
- “code of practice” (實務守則) includes—
- (a) a standard;
 - (b) a specification; and
 - (c) any other documentary form of practical guidance;
- “committee” (委員會) means a committee established under section 6(1) or a provision of Schedule 1;
- “Council” (管理局) means the Council on Human Reproductive Technology established under section 4(1);
- “designated public officer” (指定公職人員) means a public officer, or a public officer belonging to a class of public officer, designated in a notice under subsection (10);
- “embryo research” (胚胎研究)—
- (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 in a notice under subsection (2)(a)(i) to be embryo research;
 - (c) excludes a procedure specified in a notice under subsection (2)(b)(i) not to be embryo research;
- “function” (職能) includes a duty;
- “in vitro fertilization” (體外受精)—
- (a) means the fertilization of an egg by sperm outside the human body, whether or not the egg was originally removed from the body of that or any other woman;
 - (b) includes any procedure involving the induction or aspiration of an egg, or the culture of an egg for the purposes of any such fertilization;
- “licence” (牌照) means a licence granted under section 23(1)(a);
- “licensee” (持牌人), in relation to a licence, means the holder of the licence;
- “negotiate” (商議), in relation to a surrogacy arrangement, includes any bid or offer in relation to the arrangement;
- “notice” (公告、通知) means notice in writing;
- “payment” (付款) means payment in money or money’s worth but does not include any payment for defraying or reimbursing—

- (a) the cost of removing, transporting or storing an embryo or gamete to be supplied;
- (b) any expenses or loss of earnings incurred by a person and attributable to the person supplying an embryo or gamete from the person's body;
- (c) in the case of a surrogacy arrangement, any expenses incurred by the surrogate mother for—
 - (i) any reproductive technology procedure; or
 - (ii) bona fide medical expenses arising from pregnancy and delivery of a child born pursuant to the arrangement;

“person responsible” (負責人), in relation to a licence, means the individual specified in the licence as the individual under whose supervision the activities authorized by the licence shall be carried on;

“practicable” (切實可行) means reasonably practicable;

“Register A” (甲登記冊) means the register kept and maintained under section 33(1);

“relevant activity” (有關活動) means an activity which consists of or involves—

- (a) the provision of a reproductive technology procedure;
- (b) the conducting of embryo research; or
- (c) the handling, storing or disposing of a gamete or embryo used or intended to be used in connection with a reproductive technology procedure or embryo research;

“reproductive technology procedure” (生殖科技程序) 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—

- (a) in vitro fertilization;
- (b) artificial insemination;
- (c) the obtaining of gametes;
- (d) manipulation of embryos or gametes outside the body;
- (e) a procedure specified in a notice under subsection (2)(a)(ii) to be a reproductive technology procedure; and
- (f) a gender selection achieved or intended to be achieved by means of a procedure which falls within this definition,

but excludes a procedure specified in a notice under subsection (2)(b)(ii) not to be a reproductive technology procedure;

“surrogacy arrangement” (代母安排) means an arrangement by virtue of which a woman to whom it relates would be a surrogate mother were she to carry a child pursuant to the arrangement;

“surrogate mother” (代母) means a woman who carries a child—

- (a) pursuant to an arrangement—
 - (i) made before she began to carry the child; and

- (ii) made with a view to any child carried pursuant to the arrangement being handed over to, and the parental rights being exercised (so far as practicable) by, another person or persons; and
 - (b) conceived by a reproductive technology procedure.
- (2) The Secretary for Health and Welfare may, by notice in the Gazette, specify a procedure—
 - (a) to be—
 - (i) embryo research; or
 - (ii) a reproductive technology procedure;
 - (b) not to be—
 - (i) embryo research; or
 - (ii) a reproductive technology procedure,subject to such terms and conditions, if any, as are specified in the notice.
- (3) It is hereby declared that a notice under subsection (2) is subsidiary legislation.
- (4) For the purposes of this Ordinance—
 - (a) in determining whether an arrangement is made with such a view as is referred to in paragraph (a)(ii) of the definition of “surrogate mother” regard may be had to the circumstances as a whole (and, in particular, where there is a promise or understanding that any payment will or may be made to the woman or for her benefit in respect of the carrying of any child pursuant to the arrangement, to that promise or understanding);
 - (b) an arrangement may be regarded as made with such a view though subject to conditions relating to the handing over of any child;
 - (c) a woman who carries a child is to be treated for the purposes of paragraph (a)(i) of that definition as beginning to carry it at the time of the placing in her of an embryo, of an egg in the process of fertilization or of sperm and eggs, as the case may be, that results in her carrying the child.
- (5) This Ordinance, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body, and in this Ordinance—
 - (a) references to embryos the creation of which was brought about in vitro (in their application to those where fertilization is complete) are to those where fertilization began outside the human body whether or not it was completed there; and
 - (b) references to embryos taken from a woman do not include embryos whose creation was brought about in vitro.
- (6) This Ordinance, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.

(7) In this Ordinance, except where otherwise stated—

- (a) embryo means a live human embryo where fertilization is complete; and
- (b) references to an embryo include an egg in the process of fertilization,

and, for this purpose, fertilization is not complete until the appearance of a 2 cell zygote.

(8) References in this Ordinance to gametes, eggs or sperm, except where otherwise stated, are references to live human gametes, eggs or sperm, but references to gametes or eggs do not include gametes or eggs in the process of fertilization unless otherwise stated.

(9) References in this Ordinance to keeping, in relation to embryos or gametes, include keeping while preserved, whether preserved by cryopreservation or in any other way, and embryos or gametes so kept are referred to in this Ordinance as “stored” (and “store” and “storage” shall be construed accordingly).

(10) The Secretary for Health and Welfare may, by notice given to the Council, designate a public officer, or a public officer belonging to a class of public officer, specified in the notice to be a public officer available to assist the Council subject to such terms and conditions, if any, as are specified in the notice.

(11) For the avoidance of doubt, it is hereby declared that the provisions of the Employment Ordinance (Cap. 57) shall not operate differently between a woman who is pregnant or confined as a result of a surrogacy arrangement (and whether or not the surrogacy arrangement is lawful) and a woman who is pregnant or confined otherwise than as the result of a surrogacy arrangement.

3. Application

This Ordinance binds the Government.

PART II

ESTABLISHMENT, FUNCTIONS AND POWERS OF COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY

4. Establishment of Council on Human Reproductive Technology

(1) There is hereby established a council to be called in English the “Council on Human Reproductive Technology” and in Chinese “人類生殖科技管理局”.

(2) Subject to subsection (3), the Chief Executive shall appoint to be members of the Council—

- (a) a Chairperson;
- (b) a deputy Chairperson;
- (c) 4 persons who are engaged in the teaching or practice of—
 - (i) obstetrics and gynaecology; or
 - (ii) any relevant activity;
- (d) 1 person who is a social worker;
- (e) 2 persons who are legally qualified;
- (f) 2 persons who—
 - (i) occupy in any organized religion any office associated with the teaching of, the giving of guidance on, or the promotion of adherence to, the precepts of the religion; or
 - (ii) are engaged in the teaching of any theology, philosophy or ethics;
- (g) 1 person who is a psychiatrist or psychologist;
- (h) 1 person who is a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
- (i) 1 person who is a sociologist;
- (j) 1 person nominated by the Secretary for Health and Welfare;
- (k) 1 person nominated by the Director of Health;
- (l) 1 person nominated by the Director of Home Affairs;
- (m) 1 person nominated by the Director of Social Welfare; and
- (n) not more than 8 other persons.

(3) The Chief Executive—

- (a) shall not appoint a public officer to be a member of the Council under subsection (2)(a) or (b);
- (b) shall ensure that less than half the membership of the Council from time to time are public officers.

(4) The Secretary for Health and Welfare shall appoint—

- (a) a Secretary to the Council; and
- (b) a legal adviser to the Council.

(5) The relevant provisions of Schedule 1 shall have effect with respect to the Council and its members.

(6) Part VII of the Interpretation and General Clauses Ordinance (Cap. 1) shall apply to the Council and appointments to the Council except in so far as it is inconsistent with the provisions of this Ordinance.

(7) Every appointment under subsection (2) shall be notified in the Gazette.

5. Functions and powers of Council

(1) The Council shall—

- (a) keep under review information about—
 - (i) embryos and any subsequent development of embryos;
 - (ii) relevant activities;
 - (iii) surrogacy arrangements,and advise the Secretary for Health and Welfare, if the Secretary asks it to do so, about those matters;
- (b) publish or otherwise make available—
 - (i) lists of premises at which relevant activities may be carried on pursuant to a licence;
 - (ii) statistics and summaries concerning relevant activities which have been carried on;
- (c) provide, to such extent as it considers appropriate, information for persons (including persons proposing to be persons)—
 - (i) to whom licences apply;
 - (ii) to whom a reproductive technology procedure is provided;or
 - (iii) providing gametes or embryos for use for the purposes of a relevant activity or surrogacy arrangement;
- (d) promote (by the dissemination of information and in other ways) informed public debate on the medical, social, moral, ethical and legal issues that arise from relevant activities and surrogacy arrangements;
- (e) liaise and co-operate with any person in any place outside Hong Kong—
 - (i) performing in that place any functions which, in the opinion of the Council, are similar (whether in whole or in part) to any of the Council's functions under this Ordinance; and
 - (ii) in respect of any matters of mutual interest concerning relevant activities and surrogacy arrangements, in particular any ethical or social issues arising therefrom; and
- (f) perform such other functions as are imposed on it under this Ordinance or any other enactment.

(2) The Council may do all such things as are necessary for, or incidental or conducive to, the better performance of its functions and in particular but without prejudice to the generality of the foregoing, may—

- (a) carry out research into the social consequences of reproductive technology procedures;
- (b) promote research into the causes of human infertility;
- (c) exercise such other powers as are conferred on it under this Ordinance or any other enactment.

(3) The Council may from time to time cause to be prepared and published by notice in the Gazette, for the guidance of persons who propose to make an application for a licence, or who are the holders of a licence, guidelines not inconsistent with this Ordinance, indicating the manner in which it proposes to perform any of its functions, or exercise any of its powers, under this Ordinance.

6. Establishment of committees

(1) The Council may establish such committees for the better performance of its functions and exercise of its powers as it thinks fit.

(2) The relevant provisions of Schedule 1 shall have effect with respect to a committee and its members.

(3) Subject to the relevant provisions of Schedule 1, the Council—

(a) may appoint—

(i) members of the Council;

(ii) persons who are not such members (including the person responsible under a licence or the licensee),
to be members of a committee; and

(b) shall—

(i) appoint the chairperson and deputy chairperson of a committee;

(ii) determine the number of members of a committee.

(4) Part VII of the Interpretation and General Clauses Ordinance (Cap. 1) shall apply to a committee and appointments to the committee except in so far as it is inconsistent with the provisions of this Ordinance.

(5) The Secretary for Health and Welfare shall appoint a Secretary to a committee.

7. Functions and powers of committees

A committee (including any committee established pursuant to a provision of Schedule 1)—

(a) shall perform such functions and may exercise such powers as are—

(i) imposed or conferred on it under this Ordinance; or

(ii) delegated to it by the Council under section 10; and

(b) may, subject to the relevant provisions of Schedule 1 and to any directions of the Council, regulate its own procedure.

8. Code of practice

(1) The Council shall prepare and maintain a code of practice giving guidance about the proper conduct of any relevant activity authorized by any licence and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.

(2) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.

(3) The Council may from time to time revise the whole or any part of the code.

(4) The Council shall publish the code as for the time being in force.

(5) The Council shall, in preparing or revising the code, consult with—

(a) persons to whom the code will or may apply; and

(b) such other interested persons,

as it thinks fit.

(6) The code, including the code as revised under subsection (3), shall not come into force until the Council publishes a notice in the Gazette—

(a) stating that it has, pursuant to this section, published the code or revised code, as the case may be; and

(b) specifying the place or places at which the code or revised code, as the case may be, is available to be obtained.

(7) The Council, in preparing or revising the code to the extent to which it relates, or may relate, to any child to be born in consequence of a reproductive technology procedure, shall treat as of paramount importance, and accept as a fundamental principle, the welfare of the child.

9. Use of code

A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but the Council—

(a) shall, in considering whether there has been any failure to comply with any conditions of a licence (including conditions referred to in section 45(2)(a), and, in particular, conditions requiring anything to be “proper” or “suitable”, take account of any relevant provision of the code; and

(b) shall, in considering, where it has power to do so, whether or not to vary, revoke or renew a licence, take into account any observance of or failure to observe the provisions of the code.

10. Delegations

(1) Subject to subsection (2), the Council may delegate in writing any of its functions and powers under this Ordinance to any committee, any member of the Council or of a committee or any designated public officer subject to such terms and conditions, if any, as it thinks fit and specified in the delegation.

- (2) The Council shall not delegate any of its functions or powers under—
- (a) subsection (1) or section 5(3), 6(1), 23, 27 or 45(2);
 - (b) any provisions of any regulations made under this Ordinance which are specified in the regulations as provisions which shall not be subject to subsection (1);
 - (c) any provisions of Schedule 1 which are specified in that Schedule as provisions which shall not be subject to subsection (1).
- (3) A delegate of the Council—
- (a) shall perform the delegated functions and may exercise the delegated powers as if the delegate were the Council; and
 - (b) shall be presumed to be acting in accordance with the relevant delegation in the absence of evidence to the contrary.

11. Issue of certificates to authorized persons

(1) The Council shall issue to each authorized person a certificate as evidence that he is an authorized person.

(2) An authorized person shall, if so requested when exercising or attempting to exercise any power conferred on him under this Ordinance, produce the certificate issued to him under subsection (1).

12. Protection of members of Council, etc.

(1) No person to whom this subsection applies, acting in good faith, shall be personally liable in damages for any act done or default made in the performance or purported performance of any function, or the exercise or purported exercise of any power, imposed or conferred on the Council under this Ordinance.

(2) The protection conferred under subsection (1) on any person to whom that subsection applies in respect of any act or default shall not in any way affect the liability of the Council for that act or default.

- (3) The persons to whom subsection (1) applies are—
- (a) any member of the Council or a committee;
 - (b) a designated public officer.

PART III

PROHIBITIONS

13. Prohibition against carrying on relevant activity except pursuant to licence

No person shall carry on a relevant activity except pursuant to a licence.

14. Prohibition against using donated gametes in surrogacy arrangement

Without prejudice to the operation of the Parent and Child Ordinance (Cap. 429), no person shall, for the purposes of a surrogacy arrangement, use gametes other than the gametes of 2 persons who are—

- (a) the parties to a marriage; and
- (b) the persons referred to in paragraph (a)(ii) of the definition of “surrogate mother” in so far as that arrangement is concerned.

15. Prohibitions in connection with embryos, against sex selection and against the provision of reproductive technology procedures to unmarried persons

(1) No person shall—

(a) for the purposes of embryo research—

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

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

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

(c) place any non-human gametes or embryo or any part thereof in any human;

(d) place any human gametes or embryo or any part thereof in any animal;

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

(f) clone any embryo.

(2) No person shall, for the purposes of a reproductive technology procedure, keep or use any fetal ovarian, or fetal testicular, tissue.

(3) No person shall, by means of a reproductive technology procedure, cause the sex of an embryo to be selected, whether directly or indirectly (including by the implantation of an embryo of a particular sex in the body of a woman), except where—

- (a) the purpose of such selection is to avoid a sex-linked genetic disease specified in Schedule 2 which may prejudice the health of the embryo (including any foetus, child or adult which may arise from the embryo); and
- (b) not less than 2 registered medical practitioners each state in writing that such selection is for that purpose and such disease would be sufficiently severe to a person suffering it to justify such selection.

(4) For the purposes of subsection (1)(b), 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.

(5) Subject to subsections (6), (7) and (8), no person shall provide a reproductive technology procedure to persons who are not the parties to a marriage.

(6) Without prejudice to the operation of section 14, subsection (5) shall not apply in the case of a reproductive technology procedure provided to a person who is to be a surrogate mother where the procedure is provided pursuant to the surrogacy arrangement under which she is to be the surrogate mother.

(7) It is hereby declared that—

- (a) subject to paragraph (b), subsection (5) shall not operate to prohibit the continuation of a reproductive technology procedure 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;
- (b) paragraph (a) shall not operate to permit any further gametes or further embryo to be placed in the body of that woman pursuant to that procedure.

(8) Subsection (5) shall not apply in the case of the reproductive technology procedure referred to in paragraph (c) of the definition of “reproductive technology procedure” in section 2(1).

16. Prohibition against commercial dealings in prescribed substance

(1) No person shall—

- (a) whether in Hong Kong or elsewhere, make or receive any payment for the supply of, or for an offer to supply, a prescribed substance intended to be used for the purposes of any reproductive technology procedure, embryo research or surrogacy arrangement;

- (b) seek to find a person willing to supply for payment a prescribed substance referred to in paragraph (a);
- (c) initiate or negotiate any arrangement involving the making of any payment for the supply of, or for an offer to supply, a prescribed substance referred to in paragraph (a); or
- (d) take part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of any arrangement referred to in paragraph (c).

(2) Without prejudice to the generality of subsection (1)(b), no person shall cause to be published or distributed, or knowingly publish or distribute, an advertisement—

- (a) inviting persons to supply for payment a prescribed substance referred to in subsection (1)(a) or offering to supply any such prescribed substance for payment; or
 - (b) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in subsection (1)(c).
- (3) In this section, “prescribed substance” (訂明物質) means—
- (a) a gamete or embryo; or
 - (b) fetal ovarian, or fetal testicular, tissue.

17. Prohibition against surrogacy arrangements on commercial basis, etc.

- (1) No person shall—
- (a) whether in Hong Kong or elsewhere, make or receive any payment for—
 - (i) initiating or taking part in any negotiations with a view to the making of a surrogacy arrangement;
 - (ii) offering or agreeing to negotiate the making of a surrogacy arrangement; or
 - (iii) compiling any information with a view to its use in making, or negotiating the making of, surrogacy arrangements;
 - (b) seek to find a person willing to do any act which contravenes paragraph (a);
 - (c) take part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include any act which contravenes paragraph (a); or
 - (d) carry out or participate in any act in furtherance of any surrogacy arrangement where he knows, or ought reasonably to know, that the arrangement is the subject of any act which contravenes paragraph (a).

(2) Without prejudice to the generality of subsection (1)(b), no person shall cause to be published or distributed, or knowingly publish or distribute, an advertisement relating to surrogacy arrangements, and whether or not the advertisement invites persons to do any act which contravenes subsection (1)(a).

18. Surrogacy arrangements unenforceable

No surrogacy arrangement is enforceable by or against any of the persons making it.

19. Declaration

It is hereby declared that a licence cannot authorize the carrying on of a relevant activity which would contravene any of the provisions of section 14, 15, 16 or 17.

20. Conscientious objection

(1) No person who has a conscientious objection to participating in a relevant activity authorized by a licence shall be under any duty, howsoever arising, to do so.

(2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.

(3) For the avoidance of doubt, it is hereby declared that a conscientious objection to participating in a relevant activity authorized by a licence may be made by the person responsible under the licence or a licensee.

PART IV

LICENCES

21. Application for licence

Subject to any regulations made under section 45(2)(e), a person may make an application to the Council to be granted a licence to carry on a relevant activity in premises specified in the application.

22. Information to be furnished

(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.

(2) For the purposes of subsection (1), the Council may require the attendance before it of an applicant who is an individual or, in the case of an applicant which is a 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.

23. Determination of application

(1) Subject to this section, upon receipt of an application for a licence, 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.

(2) The Council shall not grant a licence to an applicant unless it is satisfied that—

(a) subject to subsection (3), 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);

(c) the individual referred to in paragraph (a)(i) has the prescribed qualifications, 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);

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

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

(f) in all the 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 this Ordinance with which it is their respective duty to comply.

(3) The Council may grant a licence to an applicant notwithstanding that the applicant is an individual who is to be the person responsible if the Council is satisfied that, in all the circumstances of the case, the fact that the licensee and the person responsible are the same person will not prejudice the discharge of the duty under section 24(1) by the person responsible.

(4) Where subsection (3) is applicable to a licence, references in this Ordinance to a licensee shall be construed with all necessary modifications to take account of the fact that the licensee and the person responsible are the same person.

(5) 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 this Ordinance shall be performed or exercised, as the case may be, 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 this Ordinance shall be read and have effect with such modifications as are necessary to take into account any such licence.

(6) Neither this section nor this section as read with sections 28(5) and (6) and 41 shall operate so as to require the Council, under any circumstances, to grant a licence where 2 or more individuals are to be the responsible person, and whether or not the Council is satisfied as to the matters referred to in subsection (2).

24. Duty of person responsible and licensee

(1) It shall be the duty of the person responsible under a licence to secure—

- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the relevant activity authorized by the licence;
- (b) that proper equipment is used;
- (c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish;
- (d) that, in all the circumstances, proper practices are used in the course of that activity; and
- (e) that the conditions of the licence are complied with.

(2) It shall be the duty of the licensee under a licence to secure that the person responsible under the licence discharges the duty under subsection (1).

(3) References in this Ordinance to the persons to whom a licence applies are references to—

- (a) the person responsible;
- (b) any person designated in the licence, or in a notice given to the Council by the person responsible or the licensee, as a person to whom the licence applies; and
- (c) any person acting under the direction of the person responsible or of any person so designated.

25. Validity of licence

A licence shall cease to be valid—

- (a) upon the expiry of—
 - (i) 3 years after the date of its last grant; or
 - (ii) such lesser period, if any, specified in the licence, whichever first occurs; or
- (b) if the licence is revoked under section 27.

26. Renewal of licence

References in this Ordinance to—

- (a) an application for a licence (howsoever expressed) shall include an application for the renewal of a licence; and
- (b) the grant of a licence (howsoever expressed) shall include the renewal of a licence,

and the other provisions of this Ordinance shall be construed accordingly.

27. Revocation and variation of licence

(1) The Council may revoke a licence if it is satisfied—

- (a) that any information given—
 - (i) in the application for the grant of the licence; or
 - (ii) under section 22 in so far as it relates to the licence, was in any material respect false or misleading;
- (b) that the premises to which the licence relates are no longer suitable for the relevant activity authorized by the licence;
- (c) that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 24(1); or
- (d) that there has been any other material change of circumstances since the licence was last granted.

(2) The Council may also revoke a licence if—

- (a) it ceases to be satisfied that—

- (i) the character of the person responsible is such as is required for the supervision of the relevant activity authorized by the licence; or
 - (ii) the licensee is a suitable person to hold a licence; or
- (b) the person responsible dies or the person responsible or the licensee is convicted of an offence against this Ordinance.
- (3) Where the Council has power to revoke a licence under subsection (1), it may instead vary any terms of the licence.
- (4) The Council may vary or revoke a licence on an application by the person responsible or the licensee.
- (5) The Council may, on an application by the licensee, vary a licence so as to designate another individual in place of the person responsible if—
 - (a) the Council is satisfied that the other individual has the prescribed qualifications, 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); and
 - (b) the application is made with the consent of the other individual.
- (6) Except on an application under subsection (5), a licence may only be varied under this section—
 - (a) so far as it relates to 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); or
 - (b) so as to extend or restrict the premises to which the licence relates.
- (7) For the avoidance of doubt, it is hereby declared that the revocation of a licence may be subject to such conditions, if any, as the Council thinks fit specified in the notice effecting the revocation.

28. Procedure for refusal, etc. of licence

- (1) Where the Council proposes to—
 - (a) refuse to grant a licence;
 - (b) grant a licence in respect of part only of the premises or relevant activity specified in the application concerned;
 - (c) grant a licence subject to conditions; or
 - (d) refuse to vary a licence so as to designate another individual in place of the person responsible,the Council shall give notice of the proposal, the reasons for it and the effect of subsection (3) to the applicant.

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

(3) 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 subsection (1) or (2) gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in subsection (4), the Council shall, before making its determination, give the person an opportunity to make representations in that way.

(4) The 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.

(5) The Council shall—

- (a) in the case of a determination to grant a licence, give notice of the determination to the licensee and the person responsible;
- (b) in the case of a determination to refuse to grant a licence, or 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; and
- (c) in the case of a determination to vary or revoke a licence, give notice of the determination to the licensee and the person responsible.

(6) The Council shall, in giving notice of a determination to—

- (a) refuse to grant a licence;
- (b) grant a licence in respect of part only of the premises or relevant activity specified in the application concerned;
- (c) grant a licence subject to conditions;
- (d) refuse to vary a licence so as to designate another individual in place of the person responsible; or
- (e) vary or revoke a licence otherwise than on an application by the licensee or the person responsible,

also give in the notice the reasons for its decision.

(7) In this section, “conditions” (條件) do not include conditions to which a licence is subject by virtue of regulations made under section 45(2)(a).

(8) It is hereby declared that conditions to which a licence is subject by virtue of regulations made under section 45(2)(a) do not need to be specified in the licence in order for the licence to be so subject.

29. Temporary suspension of licence

(1) Where the Council—

- (a) has reasonable grounds to suspect that there are grounds for revoking a licence under section 27; and
- (b) is of the opinion that the licence should immediately be suspended,

it may by notice suspend the licence for such period not exceeding 3 months as may be specified in the notice.

(2) Notice under subsection (1) shall be given to the licensee under the licence to which the notice relates and the person responsible under the licence (or, where the person responsible has died or appears to the Council to be unable because of incapacity to discharge the duty under section 24(1), to some other person to whom the licence applies) and the Council may, by a further notice to the licensee and that person, renew or further renew the notice under subsection (1) for such further period not exceeding 3 months as may be specified in the renewal notice.

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

(4) The Council may at any time revoke a notice under this section.

(5) For the avoidance of doubt, it is hereby declared that—

- (a) a notice under this section may be subject to such conditions, if any, as the Council thinks fit specified in the notice;
- (b) a notice under this section may be revoked and replaced by another notice under this section whether or not any conditions specified in the first-mentioned notice have been contravened;
- (c) a licence the subject of a notice under this section may be revoked under section 27 whether or not any conditions specified in the notice have been contravened.

30. Display of licence

The person responsible under a licence shall cause the licence or an exact copy thereof to be exhibited at all times in a conspicuous position in the premises to which the licence relates.

31. Lost, etc. licences

Where a licence has been lost, defaced or destroyed, the Council may issue to the holder thereof another licence in like terms, and any such licence so issued shall, for the purposes of this Ordinance, be deemed to have been granted under section 23(1)(a).

32. Voluntary surrender of licence

(1) Without prejudice to the generality of section 27(4) but subject to this section, a licensee may surrender his licence by lodging it at the office of the Council.

(2) The surrender of a licence under subsection (1) 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.

(3) The Council may refuse to accept the surrender of a licence under subsection (1) where the licensee has been served a notice under section 28(2) in relation to the revocation of the licence, or the Council has reasonable grounds to suspect that there are grounds for revoking the licence under section 27, unless and until the Council—

(a) revokes the licence; or

(b) gives notice to the licensee that it will not revoke the licence.

(4) Immediately upon the surrender of a licence under subsection (1) having effect in accordance with subsection (2), 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 this Ordinance prior to the surrender.

PART V

ACCESS TO INFORMATION

33. Register A

(1) Without prejudice to the generality of section 45(1)(a), the Council shall keep and maintain a register which shall contain any information obtained by the Council which falls within subsection (2).

(2) Information falls within this subsection if—

(a) it relates to the provision of a reproductive technology procedure where a child born or intended to be born in consequence of the procedure would not be created from the gametes solely of the parties to a marriage who it is proposed will be the parents of the child; and

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

(3) An adult may by notice given to the Council require the Council to comply with a request under subsection (4), and the Council shall do so if—

- (a) the information contained in Register A shows that the adult was, or may have been, born in consequence of a reproductive technology procedure which falls within subsection (2); and
- (b) the adult has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.

(4) The adult may request the Council to give him notice stating whether or not the information contained in Register A shows that a person other than a parent of the adult would or might, but for sections 9, 10 and 11 of the Parent and Child Ordinance (Cap. 429), be a parent of the adult and, if it does show that—

- (a) giving the adult so much of that information as relates to the person concerned as the Council is required by regulations made under section 45(1)(d) to give (but no other information); or
- (b) stating whether or not that information shows that, but for those sections, the adult, and a person specified in the request as a person whom the adult proposes to marry, would or might be related.

(5) Regulations made under section 45(1)(d) shall not require the Council to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Council could not have been required to give information of the kind in question.

(6) No information contained in Register A shall be removed therefrom at any time before the expiration of 80 years from the date on which the information was first entered in Register A.

(7) In this section, “adult” (成年人) means a person who has attained the age of 16 years.

34. Secrecy

(1) No person who is or has been—

- (a) an authorized person; or
- (b) a person to whom a licence applies or the holder of a licence,

shall disclose any information contained or required to be contained in Register A.

(2) Subsection (1) shall not apply to any disclosure of information made—

- (a) to a person as an authorized person;
- (b) to a person to whom a licence applies, or a licensee, for the purposes of his functions as such;

- (c) so that no individual to whom the information relates can be identified;
- (d) in accordance with section 33;
- (e) pursuant to an order under section 35(1);
- (f) to the Registrar within the meaning of section 36 pursuant to a request under that section; or
- (g) for the purposes of establishing, in any proceedings relating to an application for an order under section 12(1) of the Parent and Child Ordinance (Cap. 429), whether the condition specified in paragraph (a) or (b) of that section is met.

(3) Subject to subsection (4), in the case of information relating to the provision of a reproductive technology procedure for an identifiable individual, subsection (1) shall not apply to a disclosure made in accordance with—

- (a) the consent in writing of the individual given before the provision of the procedure; or
- (b) the consent in writing of the individual given after the provision of the procedure if, and only if, the consent were obtained in accordance with a permission in writing given by the individual—
 - (i) before the provision of the procedure; and
 - (ii) to the effect that the individual may be contacted after the provision of the procedure for the purpose of ascertaining whether or not the individual will consent to a disclosure of information relating to the provision of the procedure to the individual, either generally or in circumstances specified in the permission.

(4) If a disclosure cannot be made under subsection (3) in relation to an identifiable individual without a disclosure of information relating to the provision of a reproductive technology procedure to another identifiable individual, then the first-mentioned disclosure shall not be made under that subsection unless the second-mentioned disclosure can also be made under that subsection.

(5) In the case of information which shows an identifiable individual was, or may have been, born in consequence of a reproductive technology procedure, subsection (1) shall not apply to a disclosure which is necessarily incidental to disclosure under subsection (3).

(6) This section shall not apply to a disclosure to an individual of information which relates only to that individual or, in the case of an individual treated with another, only to that individual and that other.

(7) It shall be deemed to be a condition of every licence that a reproductive technology procedure that may be provided pursuant to the licence shall not be provided for an identifiable individual unless the individual has, before the provision of the procedure, given or refused to give—

- (a) a consent referred to in subsection (3)(a); or
- (b) a permission referred to in subsection (3)(b).

35. Disclosure in interests of justice

(1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 9, 10 and 11 of the Parent and Child Ordinance (Cap. 429) falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Council—

- (a) to disclose whether or not any information relevant to that question is contained in Register A; and
- (b) if it is, to disclose so much of it as is specified in the order,

but such an order may not require the Council to disclose any information which may identify any individual by virtue of whose gametes the information falls within section 33(2).

(2) The court shall not make an order under subsection (1) unless it is satisfied that the interests of justice require it to do so, taking into account—

- (a) any representations made by any individual who may be affected by the disclosure; and
- (b) the welfare of any minor who may be affected by the disclosure.

(3) If the proceedings before the court are civil proceedings, the court—

- (a) may direct that the whole or any part of the proceedings on the application for an order under subsection (1) shall be heard in camera; and
- (b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.

(4) An application for a direction under subsection (3) shall be heard in camera unless the court otherwise directs.

(5) In this section, “court” (法庭) includes a magistrate.

36. Information to be provided to Registrar

(1) In this section, “Registrar” (登記官) means Registrar within the meaning of the Births and Deaths Registration Ordinance (Cap. 174).

(2) This section applies where a claim is made before the Registrar that a man is or is not the father of a child and it is necessary or desirable for the purpose of any function of the Registrar to determine whether the claim is or may be well-founded.

(3) The Council shall comply with any request made by the Registrar by notice to the Council to disclose whether any information in Register A tends to show that the man may be the father of the child by virtue of section 10 of the Parent and Child Ordinance (Cap. 429) and, if it does, disclose that information.

PART VI

ENFORCEMENT AND OFFENCES

37. Power of authorized persons to enter premises to which licence relates

(1) An authorized person may at any reasonable time enter and inspect any premises to which a licence relates and therein—

(a) take possession of anything which he has reasonable grounds to believe may be required for the purpose of—

(i) any function of the Council relating to the grant, variation, suspension or revocation of licences; or

(ii) being used in evidence in any proceedings for an offence against this Ordinance,

and retain it for so long as it may be required for that purpose; and

(b) for that purpose, take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.

(2) In subsection (1)—

(a) the references to things include information recorded in any form; and

(b) the reference to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

(3) Nothing in this Ordinance makes it unlawful for an authorized person to keep any embryo or gametes pursuant to that person's functions as such.

(4) An authorized person shall not exercise his power under subsection (1) in respect of any premises in such a way as to unduly disrupt any activities being lawfully carried on in the premises, whether by the licensee under the licence which relates to the premises or any other person.

(5) Where an authorized person exercises his power under subsection (1), the licensee under the licence concerned shall, without charge, afford the authorized person such facilities or assistance as the authorized person may reasonably require for the purposes of the inspection concerned.

38. Power of authorized persons to enter premises

(1) A magistrate may issue a warrant under this section if satisfied by information upon oath by an authorized person that there are reasonable grounds for believing that an offence against this Ordinance is being, or has been, committed on any premises, and whether or not a licence relates to those premises.

(2) A warrant under this section shall authorize any named authorized person, together with such assistants as may be necessary—

(a) to enter the premises specified in the warrant, using such force as is reasonably necessary for the purpose; and

(b) to search the premises and—

(i) take possession of anything which he has reasonable grounds to believe may be required to be used in evidence in any proceedings for an offence against this Ordinance; or

(ii) take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.

(3) A warrant under this section shall continue in force until the end of the period of 30 days beginning with the day on which it is issued.

(4) Anything of which possession is taken under this section may be retained—

(a) for a period of 6 months; or

(b) if within that period proceedings to which the thing is relevant are commenced against any person for an offence against this Ordinance, until the conclusion of those proceedings.

(5) In this section—

(a) the references to things include information recorded in any form; and

(b) the reference in subsection (2)(b)(i) to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

(6) Without prejudice to the generality of section 11(2), where an authorized person, pursuant to a warrant issued under this section, exercises his power under subsection (2) in respect of the premises specified in the warrant, he shall produce the warrant for inspection by any person found in those premises who questions his authority to exercise that power in respect of those premises.

(7) This section shall not operate to prejudice the generality of section 37.

39. Offences

(1) A person who contravenes section 13, 14, 15(1), (2), (3) or (5), 16(1) or (2) or 17(1) or (2), or any condition specified in a notice mentioned in section 27(7) or under section 29 or 32(2), or the condition specified in section 34(7), commits an offence and is liable—

(a) on a first conviction, to a fine at level 4 and to imprisonment for 6 months;

(b) on a subsequent conviction, to a fine at level 6 and to imprisonment for 2 years.

(2) 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 and is liable on conviction to a fine at level 4 and to imprisonment for 6 months.

(3) A person who discloses any information in contravention of section 34 commits an offence and is liable—

(a) on a first conviction, to a fine at level 4 and to imprisonment for 6 months;

(b) on a subsequent conviction, to a fine at level 6 and to imprisonment for 2 years.

(4) A person who—

(a) fails to comply with a requirement made by virtue of section 37(1)(b) or (2)(b) or 38(2)(b)(ii) or (5)(b); or

(b) intentionally obstructs the exercise of any rights conferred by a warrant issued under section 38,

commits an offence and is liable on conviction to a fine at level 4 and to imprisonment for 6 months.

(5) A person to whom a licence applies or the licensee who gives or receives any money or other benefit, not authorized under this Ordinance, in respect of any supply of gametes or embryos, commits an offence and is liable on conviction to a fine at level 4 and to imprisonment for 6 months.

(6) It is a defence for a person (“the defendant”) charged with an offence of doing a thing which, under section 13, cannot be done except pursuant to a licence to show—

(a) that the defendant was acting under the direction of another; and

- (b) that the defendant believed on reasonable grounds—
 - (i) that the other person was at the material time the person responsible under a licence or a person designated by virtue of section 24(3)(b) as a person to whom a licence applied; and
 - (ii) that the defendant was authorized by virtue of the licence or directions to do that thing.

(7) It is a defence for a person charged with an offence against this Ordinance to show—

- (a) that at the material time he was a person to whom a licence applied; and
- (b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.

(8) Where the person responsible under a licence has committed an offence against this Ordinance, the licensee shall be guilty of the like offence unless the licensee shows that the act or omission constituting the offence took place without his knowledge or consent.

40. Consent to prosecution

No proceedings for an offence against this Ordinance shall be instituted except by or with the consent of the Secretary for Justice.

PART VII

MISCELLANEOUS

41. Appeals against certain decisions of Council

Any person aggrieved by a decision made in respect of him by the Council where the decision is—

- (a) a determination referred to in section 28(5) to which section 28(6) applies; or
- (b) the suspension of a licence under section 29,

may appeal to the Administrative Appeals Board against that decision.

42. Power of Council to specify forms

(1) Subject to subsection (2), the Council may specify the form of any licence or application under this Ordinance and the form of such other documents required for the purposes of this Ordinance as it thinks fit.

(2) The Council's power under subsection (1) shall be subject to any express requirement under this Ordinance for a licence or application under this Ordinance to comply with that requirement, but that requirement shall not restrict the exercise of that power in respect of the licence or application, as the case may be, to the extent that, in the opinion of the Council, its exercise of that power in respect of that licence or application, as the case may be, does not contravene that requirement.

(3) The Council's power under subsection (1) may be exercised in such a way as to—

- (a) include in a form specified under that subsection a statutory declaration—
 - (i) to be made by the person completing the form; and
 - (ii) as to whether the particulars contained in the form are true and correct to the best of that person's knowledge and belief;
 - (b) specify 2 or more forms of any licence, application or other document referred to in that subsection, whether as alternatives, or to provide for particular circumstances or particular cases, as the Council thinks fit.
- (4) A form specified under this section shall be—
- (a) completed in accordance with such directions and instructions as are specified in the form;
 - (b) accompanied by such documents as are specified in the form; and
 - (c) if the completed form is required to be provided to—
 - (i) the Council;
 - (ii) another person on behalf of the Council; or
 - (iii) any other person,so provided in the manner, if any, specified in the form.

43. Giving of notice

A notice (howsoever described) which under this Ordinance is required to be, or which may be, given to a person (howsoever described) shall, in the absence of evidence to the contrary, be deemed to be so given if—

- (a) in the case of an individual, it is—
 - (i) delivered to him;
 - (ii) left at his last known address for service, or at his last known place of residence or business, in Hong Kong;
 - (iii) sent by post to him at his last known address for service, or at his last known postal address, in Hong Kong; or

- (iv) sent by telex, facsimile transmission or other similar method to him at his last known address for service, or at his last known postal address, or at his last known place of residence or business, in Hong Kong;
- (b) in the case of a company, it is—
 - (i) given to or served on a director or manager of the company;
 - (ii) left at the company's last known address for service, or at its last known place of business, in Hong Kong;
 - (iii) sent by post to the company at its last known address for service, or at its last known postal address, in Hong Kong; or
 - (iv) sent by telex, facsimile transmission or other similar method to the company at its last known address for service, or at its last known postal address, or at its last known place of business, in Hong Kong;
- (c) in the case of a partnership, it is—
 - (i) delivered, left or sent in accordance with paragraph (a) in respect of any partner who is an individual; or
 - (ii) given, served, left or sent in accordance with paragraph (b) in respect of any partner which is a company;
- (d) in the case of a person ("attorney") holding a power of attorney under which the attorney is authorized to accept service in respect of another person, it is—
 - (i) delivered, left or sent in accordance with paragraph (a) where the attorney is an individual;
 - (ii) given, served, left or sent in accordance with paragraph (b) where the attorney is a company;
 - (iii) delivered, left or sent in accordance with paragraph (a) in respect of any partner who is an individual where the attorney is a partnership; or
 - (iv) given, served, left or sent in accordance with paragraph (b) in respect of any partner which is a company where the attorney is a partnership.

44. Regulations—fees

- (1) The Financial Secretary may make regulations to prescribe the fees to be paid to the Council in respect of—
 - (a) any application under this Ordinance to the Council;
 - (b) the provision of any service or facility connected with licences or any other matter to which this Ordinance relates.

(2) The amount of any fee prescribed in regulations made under subsection (1) 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 regulations.

(3) The Council may refuse to act in connection with anything in respect of which a prescribed fee or part of a prescribed fee has not been paid.

(4) The Council shall cause all prescribed fees paid to it to be paid into the general revenue.

(5) Unpaid prescribed fees shall constitute a debt due to the Government and shall be recoverable summarily as a civil debt within the meaning of the Magistrates Ordinance (Cap. 227).

(6) No prescribed fee shall be reduced, waived or refunded except in such circumstances, if any, as are specified in regulations made under subsection (1).

45. Regulations—general

(1) The Secretary for Health and Welfare may make regulations for all or any of following matters—

- (a) the registers to be kept and maintained by the Council in addition to Register A;
- (b) without prejudice to the generality of section 5(1)(a), information to be furnished to the Secretary for Health and Welfare concerning the activities of the Council in any period specified in the regulations;
- (c) specifying a relevant activity which a licence, or a licence belonging to a class of licence specified in the regulations, shall not authorize notwithstanding any other provision of this Ordinance;
- (d) subject to section 33(5), specifying the information required to be given under section 33(4)(a);
- (e) imposing restrictions on the disclosure of information which is not information falling within section 34(1) but is information obtained by an authorized person, a person to whom a licence applies, or a licensee, on terms or in circumstances requiring it to be held in confidence.

(2) The Council may make regulations for all or any of the following matters—

- (a) without prejudice to the generality of section 23(1)(a), the conditions to be attached to—
 - (i) every licence; or

- (ii) every licence belonging to a class of licence specified in the regulations;
- (b) the qualifications to be met by an individual designated in an application for a licence as the person under whose supervision the relevant activity to be authorized by the licence is to be carried out;
- (c) the registers and other records to be kept and maintained by—
 - (i) every holder of a licence (including any person to whom the licence applies); or
 - (ii) every holder of a licence (including any person to whom the licence applies) belonging to a class of licence specified in the regulations;
- (d) the information to be furnished to the Council—
 - (i) by—
 - (A) every holder of a licence (including any person to whom the licence applies); or
 - (B) every holder of a licence (including any person to whom the licence applies) belonging to a class of licence specified in the regulations; and
 - (ii) which may be reasonably required for the purposes of enabling or assisting the Council to perform its functions or exercise its powers under this Ordinance and, without limiting the generality of the foregoing, in relation to all or any of the following matters—
 - (A) the relevant activity authorized by the licence;
 - (B) the premises to which the licence relates;
 - (C) the persons to whom the licence applies;
 - (D) such particulars as may be required to enable the Council to comply with any regulations made under subsection (1);
- (e) specifying a class of premises to which any premises specified in an application for a licence are required to belong;
- (f) specifying the maximum period or periods of storage of embryos, gametes or other biological material used or to be used for the purposes of a relevant activity, including specifying the means of disposal of such embryos, gametes or material;
- (g) regulating (including prohibiting in whole or in part) the importation or exportation of sperm or other biological material used or to be used for the purposes of a relevant activity;
- (h) the receipt of a complaint about an applicant for a licence, a person responsible under a licence or the licensee;
- (i) the investigation into a complaint referred to in paragraph (h);

- (j) the inquiry into a complaint referred to in paragraph (h) to determine whether the Council should refuse to grant a licence to an applicant, revoke a licence or suspend a licence;
 - (k) the procedure to be followed in lodging a complaint referred to in paragraph (h), an investigation referred to in paragraph (i) or an inquiry referred to in paragraph (j).
- (3) Without prejudice to the generality of regulations which may be made under subsection (2)(a), conditions referred to in that subsection may—
- (a) prohibit, except in such circumstances, if any, as are specified in the regulations—
 - (i) the storage of an embryo or gametes, or the use of an embryo or gametes for the purposes of a relevant activity, after the death of any person—
 - (A) for whom the embryo or gametes, as the case may be, is or are stored; or
 - (B) who provided the embryo or gametes, as the case may be; or
 - (ii) the alteration, for the purposes of a relevant activity, of the genetic structure of an ovum, sperm or embryo; or
 - (b) specify a period or occurrence after which a class of embryos or gametes specified in the regulations may no longer be—
 - (i) stored; or
 - (ii) used for the purposes of a relevant activity.
- (4) Without prejudice to the generality of regulations which may be made under subsection (2)(h), (i), (j) or (k), such regulations may specify a committee (which may be a committee required by Schedule 1 to be established) to receive a complaint referred to in that subsection, to carry out an investigation referred to in that subsection, and to make a report to the Council as to the outcome of the investigation together with a recommendation as to the course of action the committee thinks the Council should take in view of the report.
- (5) Any regulations made under this section may—
- (a) empower the Council to grant exemptions from the regulations, either generally or in any particular case;
 - (b) make different provisions for different circumstances and provide for a particular case or class of case;
 - (c) be made so as to apply only in such circumstances as are specified in the regulations;
 - (d) provide for an appeal—
 - (i) to such person or body as may be referred to in, or established under, the regulations;
 - (ii) against any decision made under the regulations by the Council; and

(iii) by any person aggrieved by any such decision made in respect of him;

(e) provide for the better carrying into effect of this Ordinance;

(f) provide for such incidental, consequential, evidential, transitional and supplemental provisions as are necessary or expedient for the purpose of giving full effect to this Ordinance.

(6) Any regulations made under this section may prescribe offences in respect of contraventions of the regulations and may provide for the imposition in respect of any such offence of a fine not exceeding level 6 and of imprisonment for a period not exceeding 2 years and, in the case of a continuing offence, to a daily penalty not exceeding \$1,000.

(7) In this section, “daily penalty” (按日罰款) means a penalty for each day on which the offence is continued after conviction therefor.

46. Amendment of Schedule 1 or 2

The Secretary for Health and Welfare may, by notice in the Gazette, amend Schedule 1 or 2.

47. Transitional

(1) Subject to subsection (2), where, immediately before the relevant day, there is an individual under whose supervision a relevant activity is being lawfully carried on in any premises, then, on and after that day—

(a) that activity shall be deemed to be authorized to be carried on in those premises pursuant to a licence (“deemed licence”) granted to that individual; and

(b) that individual shall be deemed to be the person responsible (“deemed person responsible”),

and the other provisions of this Ordinance shall be construed accordingly.

(2) Paragraphs (a) and (b) of subsection (1) shall cease to apply in relation to the relevant activity and individual referred to in that subsection immediately upon—

(a) the expiration of 30 days after the relevant day except where the deemed person responsible has, before the expiration of that period, given a notice to the Council stating—

(i) his name and address for service; and

(ii) the address of the premises at which that activity is being carried on;

- (b) the expiration of 6 months after that day except where an application is made to the Council before the expiration of that period for the grant of a licence to authorize the carrying on of that activity in those premises (and whether or not the deemed person responsible is to be designated in the licence for the purposes of section 23(2)(a)); or
- (c) the determination under section 23(1) of that application,

whichever first occurs.

(3) In this section, “relevant day” (有關日期) means the day on which section 13 comes into operation.

48. Consequential amendments

The enactments specified in Schedule 3 are amended as set out in that Schedule.

SCHEDULE 1

[ss. 2(1), 4(5), 6(2) & (3),
7, 10(2)(c), 45(4) & 46]

PROVISIONS WITH RESPECT TO COUNCIL AND COMMITTEES AND THEIR MEMBERS

PART 1

COUNCIL AND ITS MEMBERS

1. Terms and conditions of appointment of members of Council

Subject to sections 2 and 3, the Chief Executive shall determine the terms and conditions of appointment of a member of the Council.

2. Terms of appointment of members of Council

(1) Subject to section 3, a member of the Council shall hold and vacate his office in accordance with the terms of his appointment and shall, on ceasing to be a member, be eligible for reappointment.

(2) A member of the Council, not being a public officer, shall be appointed for a term not exceeding 3 years.

(3) A member of the Council, not being a public officer, may at any time by notice given to the Chief Executive resign his office.

3. Chief Executive may, etc. in certain circumstances declare office of member of Council to be vacant

(1) If the Chief Executive is satisfied that a member of the Council, not being a public officer—

- (a) has been absent from 3 consecutive meetings of the Council without the permission of the Council;
- (b) has become bankrupt or made an arrangement with his creditors;
- (c) is incapacitated by physical or mental illness;
- (d) has ceased to be of the capacity by virtue of which he was appointed; or

(e) is otherwise unable or unfit to discharge the functions of a member, the Chief Executive may declare his office as a member of the Council to be vacant, and shall notify the fact in such manner as the Chief Executive thinks fit; and upon such declaration the office shall become vacant.

(2) If a member of the Council becomes the person responsible under a licence or the licensee, the Chief Executive shall declare his office as a member of the Council vacant, and shall notify the fact in such manner as the Chief Executive thinks fit; and upon such declaration the office shall become vacant.

4. Quorum of Council, etc.

(1) The quorum of the Council shall be not less than half the members thereof for the time being and, while a member is disqualified from taking part in a decision or deliberation of the Council in respect of a matter, he shall be disregarded for the purpose of constituting a quorum of the Council for deciding, or deliberating on, that matter.

(2) All matters for determination at a meeting of the Council shall be decided by a majority of votes of the members present and voting and where there is an equality of votes—

(a) the Chairperson;

(b) if the Chairperson is absent or disqualified as referred to in subsection (1), the deputy Chairperson;

(c) if both the Chairperson and the deputy Chairperson are absent or so disqualified, any other member of the Council presiding,

shall have a casting vote in addition to his original vote.

5. Procedure of Council

Subject to the provisions of this Schedule, the Council shall have power to regulate its own procedure including the manner in which decisions of the Council may be made by a quorum of its members otherwise than at a meeting of the Council.

PART 2

COMMITTEES AND THEIR MEMBERS

6. Committees required to be established

Without prejudice to the generality of section 6(1) of this Ordinance, the Council shall, not later than 6 months after this section comes into operation—

(a) establish a committee, to be called in English the “Ethics Committee” and in Chinese “倫理委員會”, to—

(i) seek the views of the public on any of the social, moral, ethical and legal issues that arise from reproductive technology procedures;

(ii) provide advice to the Council on any of those issues, whether in consequence of the committee’s function under subparagraph (i) or otherwise; and

(iii) liaise and co-operate with any other committee or body concerned with any of those issues, and whether or not the committee or body is established pursuant to a licence;

(b) establish a committee, to be called in English the “Inspection Committee” and in Chinese “視察委員會”, to—

(i) conduct inspections of premises for the purposes of paragraph (d) of section 23(2) of this Ordinance;

(ii) make recommendations to the Council in respect of—

(A) the grant of licences;

(B) any conditions to which any licence, or class of licence, may be subject;

(c) establish a committee, to be called in English the “Investigation Committee” and in Chinese “調查委員會”, to conduct an investigation into any matter which may give rise to the Council exercising any of its powers under section 27(1), (2) or (3) or 29 of this Ordinance.

7. Chairpersons of committees

The chairperson of a committee shall be appointed from amongst members of the committee who are also members of the Council.

PART 3

PROVISIONS OF SCHEDULE NOT SUBJECT TO DELEGATION

8. Council not to delegate certain functions and powers

The Council shall not delegate under section 10(1) of this Ordinance any functions or powers imposed or conferred on it under section 5 or 6.

SCHEDULE 2

[ss. 15(3)(a)
& 46]

SEX-LINKED GENETIC DISEASES

Addison's disease with cerebral sclerosis (Addison 病 (並有腦硬化))
Adrenoleucodystrophy (腎上腺白質營養不良)
Adrenal hypoplasia (腎上腺發育不良)
Agammaglobulinaemia, Bruton type (血球蛋白血病 (Bruton 型))
Agammaglobulinaemia, Swiss type (血球蛋白血病 (瑞士型))
Albinism, ocular (眼部白化病)
Albinism-deafness syndrome (白化病——耳聾綜合症)
Aldrich syndrome (Aldrich 綜合症)
Alport syndrome (Alport 綜合症)
Amelogenesis imperfecta, hypomaturation type (釉質生長不全 (成熟低下型))
Amelogenesis imperfecta, hypoplastic type (釉質生長不全 (發育不良型))
Anaemia, hereditary hypochromic (遺傳性低色數性貧血)
Angiokeratoma (Fabry's disease) (血管角質瘤 (Fabry 病))
Cataract, congenital (先天性白內障)
Cerebellar ataxia (小腦共濟失調)
Cerebral sclerosis, diffuse (擴散性腦硬化)
Charcot-Marie-Tooth peroneal muscular atrophy (Charcot-Marie-Tooth 腓骨肌萎縮症)
Choroideraemia (無脈絡膜症)
Choroidoretinal degeneration (脈絡膜視網膜變質)
Coffin-Lowry syndrome (Coffin-Lowry 綜合症)
Colour blindness, Deutan type (色盲 (綠色系列型))
Colour blindness, Protan type (色盲 (紅色系列型))
Diabetes insipidus, nephrogenic (腎原性尿崩症)
Diabetes insipidus, neurohypophyseal (尿崩症 (神經垂體型))
Dyskeratosis congenita (先天性角化不良)
Ectodermal dysplasia, anhidrotic (外胚層發育不全 (無汗型))
Ehlers-Danlos syndrome, type V (Ehlers-Danlos 綜合病 (第 V 類型))
Faciogenital dysplasia (Aarskog syndrome) (面生殖發育不全 (Aarskog 綜合症))

- Focal dermal hypoplasia (X-linked dominant, male lethal) (局灶性皮膚發育不良(與 X 染色體有關連的顯性, 對男性而言可致死))
- Glucose 6-phosphate dehydrogenase deficiency (葡糖 6 磷酸脫氫酶缺乏)
- Glycogen storage disease, type VIII (糖原貯積症(第 VIII 類型))
- Gonadal dysgenesis (XY female type) (性腺發育不全(XY 女性類型))
- Granulomatous disease (chronic) (慢性肉芽腫病)
- Haemophilia A (血友病 A)
- Haemophilia B (血友病 B)
- Hydrocephalus (aqueduct stenosis) (腦積水(中腦水管狹窄))
- Hypophosphataemic rickets (低磷酸血性佝僂病)
- Ichthyosis (steroid sulphatase deficiency) (魚鱗癬(steroid sulphatase 缺乏))
- Incontinentia pigmenti (X-linked dominant, male lethal) (色素失節症(與 X 染色體有關連的顯性, 對男性而言可致死))
- Kallmann syndrome (Kallmann 綜合症)
- Keratosis follicularis spinulosa (Spinulosa 毛囊角化病)
- Lesch-Nyhan syndrome (hypoxanthine-guanine-phosphoribosyl transferase deficiency) (Lesch-Nyhan 綜合症(次黃嘌呤——鳥嘌呤——磷酸核糖轉移酶缺乏))
- Lowe (oculocerebrorenal) syndrome (Lowe (眼腦腎) 綜合症)
- Macular dystrophy of the retina (視網膜黃斑營養不良)
- Menkes syndrome (Menkes 綜合症)
- Mental retardation, FMRI type (智力遲緩(FMRI 型))
- Mental retardation, FRAXE type (智力遲緩(FRAXE 型))
- Mental retardation, MRXI type (智力遲緩(MRXI 型))
- Microphthalmia with multiple anomalies (Lenz syndrome) (小眼症(並有多種畸型)(Lenz 綜合症))
- Mucopolysaccharidosis II (Hunter syndrome) (黏多糖貯積病 II (Hunter 綜合症))
- Muscular dystrophy, Becker type (肌營養不良(Becker 型))
- Muscular dystrophy, Duchenne type (肌營養不良(Duchenne 型))
- Muscular dystrophy, Emery-Dreifuss type (肌營養不良(Emery-Dreifuss 型))
- Myotubular myopathy (肌小管肌病)
- Night blindness, congenital stationary (先天性靜止性夜盲症)
- Norrie's disease (pseudoglioma) (Norrie's 病(假性神經膠質瘤))
- Nystagmus, oculomotor or 'jerky' (眼球震顫(眼球運動的或抽動的))
- Ornithine transcarbamylase deficiency (type I hyperammonaemia) (鳥氨酸甲酰轉移酶缺陷症(高氨血症第 I 類型))
- Orofaciodigital syndrome (type I) (X-linked dominant, male lethal) (口——面——指(趾) 綜合症(第 I 類型)(與 X 染色體有關連的顯性, 對男性而言可致死))
- Perceptive deafness, DNFZ type (感覺性聾症(DNFZ 型))
- Perceptive deafness, with ataxia and loss of vision (感覺性聾症(並有共濟失調和喪失視力))
- Phosphoglycerate kinase deficiency (磷酸甘油酸激酶缺乏)
- Phosphoribosylpyrophosphate (PRPP) synthetase deficiency (磷酸核糖焦磷酸合成酶缺乏)
- Reifenstein syndrome (Reifenstein 綜合症)
- Retinitis pigmentosa (視網膜色素變性)
- Retinoschisis (視網膜裂)
- Spastic paraplegia (痙攣性麻痺)
- Spinal muscular atrophy (脊椎肌萎縮)
- Spondyloepiphyseal dysplasia tarda (遲發性脊椎骨骺發育不全)

Testicular feminization syndrome (睪丸女性化綜合症)

Thrombocytopenia, hereditary (遺傳性血小板減少症)

Thyroxine-binding globulin, absence or variants of (甲狀腺素——結合球蛋白缺乏或變種)

Xg blood group system (Xg 血型系統)

SCHEDULE 3

[s. 48]

CONSEQUENTIAL AMENDMENTS

Offences against the Person Ordinance

1. Medical termination of pregnancy

Section 47A(8) of the Offences against the Person Ordinance (Cap. 212) is repealed and the following substituted—

(8) For the purposes of sections 46 and 47, anything done with intent to procure a woman's miscarriage (or, in the case of a woman carrying more than one foetus, her miscarriage of any foetus) is unlawfully done unless authorized by virtue of the provisions of this section and, in the case of a woman carrying more than one foetus, anything done with intent to procure the miscarriage of any foetus is authorized by those provisions if—

- (a) the ground for termination of the pregnancy specified in subsection (1)(b) applies in relation to any foetus and the thing is done for the purpose of procuring the miscarriage of that foetus; or
- (b) any of the other grounds for termination of the pregnancy specified in those provisions applies.”.

Administrative Appeals Board Ordinance

2. Schedule amended

The Schedule to the Administrative Appeals Board Ordinance (Cap. 442) is amended by adding—

- “37. Human Reproductive Technology Ordinance (47 of 2000)
- (a) A determination of the Council on Human Reproductive Technology referred to in section 28(5) to which section 28(6) applies.
 - (b) The suspension of a licence under section 29.”.

Sex Discrimination Ordinance

3. Reproductive technology

Section 56B(2) of the Sex Discrimination Ordinance (Cap. 480) is repealed and the following substituted—

“(2) In this section, “reproductive technology procedure” (生殖科技程序) has the meaning assigned to it by section 2(1) of the Human Reproductive Technology Ordinance (47 of 2000).”.

4. Further exceptions to this Ordinance

Schedule 5 is amended—

- (a) in Part 1, in section 1, by repealing the definition of “reproductive technology procedure” and substituting—
 ““reproductive technology procedure” (生殖科技程序) has the meaning assigned to it by section 2 of the Human Reproductive Technology Ordinance (47 of 2000).”;
- (b) in Part 2, in column 3 of item 4, by repealing “生育” and substituting “生殖”.

Personal Data (Privacy) Ordinance

5. Section added

The Personal Data (Privacy) Ordinance (Cap. 486) is amended by adding—

“63A. Human embryos, etc.

(1) Personal data which consist of information showing that an identifiable individual was, or may have been, born in consequence of a reproductive technology procedure within the meaning of the Human Reproductive Technology Ordinance (47 of 2000) are exempt from the provisions of data protection principle 6 and section 18(1)(b) except so far as their disclosure under those provisions is made in accordance with section 33 of that Ordinance.

(2) Where a data access request relates to personal data which are or, if the data existed, would be exempt from section 18(1)(b) by virtue of subsection (1), then the data are also exempt from section 18(1)(a) if the interest protected by that exemption would be likely to be prejudiced by the disclosure of the existence or non-existence of the data.”.