COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY

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圖文傳真

By Post

20 March 2009

To: All Persons Responsible Reproductive Technology (RT) Centres

Dear Sir/Madam,

Council's Recommendations for the reference of Persons Responsible

I write to inform you that the Council on Human Reproductive Technology has completed processing the first round of applications for licence under the Human Reproductive Technology Ordinance (the Ordinance). In the course of considering these applications, the Council has made a number of observations and come up with certain recommendations. These recommendations are supplementary to the Council's Code of Practice (the Code) and focus on areas that require particular attention by the Persons Responsible of RT centres licensed under the Ordinance. As directed by the Council, I now attach at Appendix these recommendations for your reference.

Should you have any enquiry, please contact the undersigned at 2961 8834 or Mr. Steven CHAN, Secretary to the Inspection Committee, at 2961 8952.

(David AU YEUNG)

Secretary, Council on Human Reproductive Technology

Council's recommendations for the reference of Persons Responsible

- 1. Provision of information to the Council regarding suitability to be a licensee and Person Responsible
- 1.1. To facilitate the Council to determine the issuance of a licence, an applicant for a licence under the Ordinance must inform the Council of any conviction in Hong Kong or elsewhere of offences punishable with imprisonment; whether he has been found guilty of misconduct in a professional respect, in Hong Kong or elsewhere; and whether there are outstanding complaints arising from or in connection with the carrying out of relevant activities involving the prospective licensee and PR.
- 2. Persons Responsible (PRs) are responsible under the Ordinance for the acts of their satellite clinics/associated doctors
- 2.1. Under section 24(1) of the Ordinance, it shall be the duty of the person responsible under a licence (PR) to ensure, amongst other matters, that in all the circumstances proper practices are used in the course of relevant activities and that the conditions of the licence are complied with. Under the same sub-section, it shall be the duty of the PR to secure 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. Section 24(3) further specifies that "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 Satellite clinics / associated doctors who are allowed to make use of the facilities of the licensed centre are considered to fall within the definition of "the persons to whom the licence applies". Therefore, for treatment centres with satellite clinics/associated doctors, the PR of the centre is fully responsible for the acts of their satellite clinics/ associated doctors. Therefore, PRs should a supervisory and proactive role to ensure that their satellite clinics/associated doctors provide the relevant RT services authorised by the licence in compliance with the Ordinance, the Licensing Manual, the Code of Practice, and the terms and conditions to which the licence is subject.

- 3. Confidentiality of patients' record during inspection visits
- 3.1. Patients seeking RT treatments may be treated for other medical problems. To protect patients' confidentiality while facilitating inspection of medical records by the Council, the RT centre is required to keep separate records for RT and non-RT procedures, or to cover up the non-RT parts of the records during the inspection.
- 4. Consent to disclosure of personal information to the Council
- 4.1. RT treatments must not be provided to patients who have not signed the consent to disclosure of personal data in connection with RT procedure/ donation (Consent Form (15)), to allow for the disclosure of personal information to the Council for the purpose of the Ordinance and the Code.
- 5. Consent to be obtained before commencement of any treatment procedure and for each cycle of treatment
- 5.1. Written consent by patients must be obtained before the commencement of any treatment procedures (including preparatory procedures such as ovarian stimulation) for each cycle of treatment.
- 6. Donor Information for the Purpose of Register A
- 6.1. Centres which carry out Artificial Insemination by Donor (AID) or RT activities using donor sperm should complete the Donor Information Form (for gamete donors) (i.e. Data Collection form (5)). Donor sperms must not be used unless sufficient information about the donor is known for the purpose of an effectual entry into Register A in respect of the reproductive technology procedure concerned, and unless such information about the donor may lawfully be and will be provided by the centre to the Council on Human Reproductive Technology for the purpose of entry into Register A.
- 7. Sperm washing centres to establish a system for checking referring practitioner/centre
- 7.1. Sperm washing centres are required to put in place a system enabling it to check that the "referring practitioner/ centre" was permitted to carry on RT procedure. The mechanism adopted by the licensed laboratories might be inspected in the

next cycle of inspection, upon consideration of applications for renewal of license.

- 8. Re-inspection of RT centres with special licensing condition(s)
- 8.1 The Council may carry out re-inspection of a licensed RT centre to ensure special conditions imposed by the Council on the licence have been complied with.