## Principles of proposed amendments to the Code of Practice on Reproductive Technology & Embryo Research

The Council on Human Reproductive Technology ("the Council") has proposed that the duration and age limits on storage of gametes (including both sperms and eggs) or embryos <u>for own use</u> should be handled as a medical issue instead of a legal issue. Hence, the Council proposed to lift the legal restrictions on storage period of gametes or embryos for own use, irrespective of the gender, age, medical or social conditions of the patients. To encourage childbearing at patients' best reproductive age and to deter unnecessary or prolonged storage without medical reasons, the Code of Practice on Reproductive Technology & Embryo Research ("the Code") would be strengthened at the same time to ensure that the public is fully aware of the associated risks.

2. Following the aforementioned recommendations of the Council, the Code is proposed to be amended in accordance with the following principles –

- (a) For patients who stored gametes/embryos for own use, additional counselling and consent form after five years of initial storage and every two years afterwards are required.
- (b) During the counselling, patients should be provided with up-to-date scientific information that is applicable to specific type(s) of gametes or embryos, such as the risks of egg retrieval procedures, declining fertility / pregnancy rate of women with aging, risks of advanced maternal age and social impacts of delayed childbearing. Patients must sign a consent form to acknowledge the receipt of such information. The counselling records should be properly documented for review by the Council when required.
- (c) More detailed data on storage of gametes or embryos for own use such as marital status, age distribution (including age of storage and usage) and type of identity document of patients would be collected through the annual statistics to be submitted by licensed centres for regulatory purposes.
- 3. Corresponding amendments to the Code are listed out as below
  - to add a clause in Section 5.2 relating to licensed centre to provide patients with up-to-date scientific information that is applicable to specific type(s) of gametes or embryos, such as the risks of egg-retrieval procedures, declining fertility / pregnancy rate of women with aging, risks of advanced maternal age and social impacts of delayed childbearing;

- (ii) to modify the clause in Section 6.7(a) as there will be no more legal limit on storage period for gametes or embryos **for own use**;
- (iii) to add a clause in Section 6.8 relating to acknowledging the receipt of upto-date scientific information that is applicable to specific type(s) of gametes or embryos, such as the risks of egg-retrieval procedures, declining fertility / pregnancy rate of women with aging, risks of advanced maternal age and social impacts of delayed childbearing when providing a written consent to begin or extend storage; and to require patients to receive proper counselling after 5 years of initial storage and every two years afterwards before signing a new consent for longer storage of gametes and embryos;
- (iv) to add the need of emphasizing declining fertility / pregnancy rate of women with aging in the general principles of counselling to Section 7.1;
- (v) to add a clause in Section 7.5 to expand the scope of counselling to include the risks of egg-retrieval procedures, declining fertility / pregnancy rate of women with aging, risks of advanced maternal age and social impacts of delayed childbearing;
- (vi) maximum storage period for gametes and embryos for patients' own use in Section 10.7 and storage period for cancer patients in Section 10.8 will be lifted;
- (vii) to update the Consent Form 1 & 2 on "Consent to Freezing and Storage of Gametes / Embryos" for amending corresponding paragraph to require patients to sign consent form and receive proper counselling from the centre **after five years of initial storage and every two years afterwards** for longer storage of gametes and embryos; to add a new paragraph for patients storing gametes/ embryos acknowledging the receipt of up-to-date scientific information that is applicable to specific type(s) of gametes or embryos about the decline in fertility/pregnancy rate of women with aging, risks of advanced maternal age and social impacts of delayed childbearing;
- (viii) to add a new Consent Form 19 on "Consent to Renewal of Freezing and Storage of Gametes / Embryos", in order to ask patient to sign consent form for renewal of freezing and storage after 5 years of initial storage and every two years afterwards and to acknowledge the receipt of proper counselling that is applicable to specific type of gametes or embryos; and

(ix) to add a new AS Form 9 on "Number of patients who stored gametes / embryos for own use" to collect more detailed data from licensed centres such as marital status, age distribution and type of identity document of patients for regulatory purposes.

4. We welcome any comments on the above principles of amendments to the Code. Please send written comments to the Secretariat of the Council by email at <a href="https://www.hrtc.action.org">https://www.hrtc.action.org</a> by fax at 2527 9849 on or before **13 April 2025**.