

## Appendix IX

### Records to be Kept and Maintained by Licensed Centres

1. Under section 45(2) of the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance), the Council may make regulation to specify the registers and other records to be kept and maintained by licensed centres.

### Registers to be Kept and Maintained by Licensed Centres

2. Licensed centres are required to keep and maintain the following -

- (a) a Donors Register which contains information on every donor of gametes or embryos stored in the licensed premises at any time on or after the commencement of the Human Reproductive Technology (Licensing) Regulation (the Regulation). Types of information to be kept in the Donors Register should include, but not limited to -
- (i) donor's clinic record number;
  - (ii) type of donated material stored in the centre;
  - (iii) date when the material was stored;
  - (iv) date when all the stored material was removed from storage or utilized; and
  - (v) outcome of treatment in which the donated material was used to facilitate checking the live birth events brought about by the material donated by any single donor.

As the Donors Register is keeping records of donors whose donated gametes or embryos are stored in the licensed premises, information on donors whose gametes or embryos are used immediately after donation and have not been stored at the licensed centre are not required to be entered into the Register;

- (b) a Patients Register which contains -
- (i) information on every person who undergoes a RT procedure in the licensed premises at any time on or after the commencement of the Regulation;
  - (ii) where the person is a woman, information on the person who was her husband when gametes were, or an embryo was, placed in her body pursuant to that procedure; and
  - (iii) where the person is a man, information on the person who was his wife when gametes were obtained from him.

Types of information to be kept in the Patients Register should include, but not limited to -

- (i) patient's clinic record number;
- (ii) name;
- (iii) gender;
- (iv) spouse's name;
- (v) dates and types of RT procedures for every treatment cycle (see Note); and
- (vi) whether the treatment involves donated gametes/embryos.

- (c) a Children Register which contains information, if available, on every child born in consequence of a RT procedure provided in the licensed premises at any time on or after the commencement of the Regulation. Types of information to be kept in the Children Register should include, but not limited to -
  - (i) clinic record numbers of parents;
  - (ii) gender; and
  - (iii) date of birth.

### **Records to be Kept and Maintained by Licensed Centres**

3. Licensed centres are required to keep and maintain the following records -
- (a) assessment of donors and patients on suitability for RT procedure;
  - (b) counselling services provided to donors and patients;
  - (c) consents and withdrawals of consent to the storage and removal from storage of gametes or embryos at the centre;
  - (d) collection and storage of gametes or embryos at the centre;
  - (e) diagnosis of collected and stored gametes or embryos at the centre;
  - (f) any amounts paid to donors in respect of donations made at the centre;
  - (g) creation or attempted creation of embryos in vitro at the centre;
  - (h) destruction or disposal at the centre of any stored gametes or embryos created in vitro;
  - (i) RT procedures carried out on a woman at the centre;
  - (j) use of gametes or embryos in a RT procedure or research at the centre;
  - (k) outcome of a RT procedure, such as clinical pregnancy, miscarriage or death of an embryo or foetus, if this information is available at the centre;
  - (l) transfer of gametes or embryos to/from another licensed centre;
  - (m) importation and exportation of any gametes or embryos from/to overseas licensed centres;
  - (n) surrogacy arrangement carried out at the centre;
  - (o) fetal reduction carried out at the centre;
  - (p) gender selection carried out at the centre;
  - (q) any complaints received by the centre; and
  - (r) any other records as determined by the Council in accordance with the Ordinance and its regulations.

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Note:

Types of procedures -

- (1) In vitro fertilization (IVF)
- (2) Artificial insemination by husband (AIH)
- (3) Artificial insemination by donor (AID)/ Donor insemination (DI)
- (4) Removal of oocytes from ovaries
- (5) Retrieval of sperm from testis
- (6) Retrieval of sperm from epididymis
- (7) Frozen-thawed/ fresh embryo transfer (ET)
- (8) Microinjection intra-fallopian transfer (MIFT)
- (9) Fallopian replacement of eggs with delayed insemination (FREDI)
- (10) Intra cytoplasmic sperm injection (ICSI)
- (11) Pre-implantation genetic diagnosis (PGD)
- (12) Sperm sorting technique
- (13) Sperm washing
- (14) In vitro maturation of oocytes

- (15) Storage of semen/sperm
- (16) Storage of oocyte
- (17) Storage of embryo
- (18) Storage of testicular tissue
- (19) Storage of ovarian tissue
- (20) Embryo donation
- (21) Oocyte donation
- (22) Assisted hatching
- (23) Embryo micromanipulation (other than assisted hatching)
- (24) Sex selection
- (25) Surrogacy arrangement
- (26) Other micromanipulation (please specify)
- (27) Others (please specify)