

Proposed Principles of Amendments to Code of Practice on Reproductive Technology and Embryo Research (“the Code”)

S/N	Issues	Background information	Related paragraphs and proposed amendments in the Code of Practice
1.	Management of incident by Licensed Centre / Person Responsible	(a) Currently, there is no mandatory incident reporting mechanism in the Code. To strengthen awareness of incident reporting among licensed centres and to ensure timely responses and prevention of similar events. It is agreed to align with private sector to introduce a mandatory reporting mechanism with reference to the Code of Practice for Private Hospital (“PH”) and Day Procedure Centre (“DPC”). (b) A written incident management and internal reporting system is necessary for the licensed centre to ensure proper handling and learning from the serious event and to delineate the responsibilities of person responsible in incident handling. (c) To align with the Code of Practices for PH and DPC as well as “sentinel event reporting mechanism” adopted by Hospital Authority, compulsory report to the Council within 24 hours upon the identification of “serious events” and submit full report to the Council within 4 weeks is proposed. (d) Serious event related to Reproductive Technology (“RT”) clinical procedures with reference to the Code of Practice of PH focused on serious event related to RT procedures, for example, surgery / interventional procedure including transfer of wrong gamete(s) / embryo(s) involving the same or wrong patient or body part, as well as ABO incompatibility blood transfusion while undergoing RT clinical procedures. (e) For serious RT related events involving laboratory and associated handling procedures, such as event that pose a risk of insemination of incorrect gamete(s) or transfer of incorrect embryo(s), mandatory reporting is required.	Addition of Chapter 16 – Handling of Incidents; and Annex I - Part 13 <i>To add –</i> <u>Management of Incident</u> 16.1 / Annex I (13.1) The person responsible must ensure that there is a written incident management and reporting system outlining the procedures to follow in case of an incident. The person responsible must review all incident reports, document the review, remedial and quality improvement measures taken, and disseminate the lesson learnt regarding the adverse event identified to all relevant staff.
2.	Timeline and Events to be reported on RT related clinical procedures	Ditto	<i>To add –</i> <u>Timeline and Events to be Reported on RT related Clinical Procedures / Laboratory Procedures</u> 16.2 / Annex I (13.2) Licensed Centres must report to the Council within 24 hours upon the identification of the following event(s), and submit full report to the Council within 4 weeks – I. Serious Events related to RT clinical procedures mean: (i) Surgery / interventional procedure including transfer of wrong gamete(s) / embryo(s) involving the same or wrong patient or body part; (ii) Retained instruments or other material after surgery / interventional procedure; (iii) ABO incompatibility blood transfusion; (iv) Medication error resulting in major permanent loss of function or death; (v) Intravascular gas embolism resulting in death or neurological damage; or (vi) Death of an inpatient from suicide (including home leave).

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3.	Events to be reported on laboratory procedures	Ditto	<i>To add –</i> 16.2 / Annex I (13.2) II. Serious Events related to RT procedures mean: (i) Laboratory and associated handling procedures which have resulted in, or pose a risk of, insemination of incorrect gamete(s) or transfer of incorrect embryo(s); (ii) Mishandling in PGT and associated biopsy handling procedures which have resulted in, or pose a risk of, an unintentional / undesired transmission of the tested genetic abnormality or related disease, excluding inherent limitation of PGT; or (iii) Inappropriate distribution, transport or logistics leading to loss of a quantity of gametes or embryos that cause insemination or transfer to be postponed or cancelled.
4.	Security on storage	(a) The current provision of the Code concerning the security on storage of gametes and embryos specifies the avoidance of loss and contamination of materials as well as the need for controlled or authorised access, but the terms adopted are relatively broad, lacking specific descriptions of required physical and technical controls. (b) In this connection, more specific measures such as logged physical access control mechanisms and real-time video monitoring with surveillance footage retained for a minimum of 6 months is proposed to enhance security of storage facilities. (c) A transition period of 12 months is proposed to facilitate centres’ compliance with the new requirements on security, inventory checking, anti-misidentification measures, as well as usage and record of training materials (i.e. issues 4-7 of this summary table).	<u>Existing related paragraphs</u> 3.8 A proper and safe storage facility must be provided to preserve the viability of gametes and embryos, to minimise chances of accident, loss or contamination. 10.1 The storage facility must be properly designed and maintained at a secure location with controlled access and away from possible sources of contamination. 10.2 The person responsible should allow access only to designated individuals in the licensed centre for whom such access is essential for their work. <u>Proposed Amendment</u> <i>To revise –</i> 10.2 The person responsible should allow access only to designated individuals in the licensed centre for whom such access is essential for their work. Logged physical access control mechanisms should be implemented to ensure restricted entry to cryo-storage areas and maintain time-stamped access for audit and traceability purposes. Real-time video monitoring shall be conducted for critical areas in the laboratory (wherever specimens are left unattended), with surveillance footage retained for a minimum of 6 months.
5.	Inventory check	(a) To ensure accurate record keeping and ensure safe keeping of gametes and embryos, licensed centres shall perform an inventory check of all stored gametes / embryos, including gametes / embryos donated for quality control or training at least once every two years, mainly to – (i) Review the purpose and duration of storage, of all gametes / embryos; and	<u>Existing related paragraph</u> 10.4 Licensed centres are responsible for maintaining the gametes and embryos in good condition through periodic review of the status of the storage equipment and records.

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		(ii) Identify and implement any follow up actions as appropriate. (b) A transition period of 12 months is proposed to facilitate centres’ compliance with the new requirements on security, inventory checking, anti-misidentification measures, as well as usage and record of training materials (i.e. issues 4-7 of this summary table).	<u>Proposed Amendment</u> <i>To revise –</i> 10.4 Licensed centres are responsible for maintaining the gametes and embryos in good condition through periodic review of the status of the storage equipment and records. Licensed centres should devise a protocol to perform an inventory check (e.g. mainly paper based, with physical verification of a reasonable proportion of the stored gametes / embryos) at least once every two years on all stored gametes/embryos, including gametes / embryos donated for quality control or training. All inventory checks shall involve – (a) Reviewing the purpose and duration of storage, of all gametes / embryos; and (b) Identifying and implementing any follow up actions as appropriate.
6.	Anti-misidentification measures	(a) To avoid misidentification of specimens and the identities of patients, husbands, or donors, the following measures are proposed to enhance security and traceability — double witnessing, documentation of checking records, and the application of appropriate tamper-evident seals. (b) A transition period of 12 months is proposed to facilitate centres’ compliance with the new requirements on security, inventory checking, anti-misidentification measures, as well as usage and record of training materials (i.e. issues 4-7 of this summary table).	<u>Existing related paragraph</u> 10.3 <i>The source of gametes and embryos should be accurately recorded and labelled in a manner which is not susceptible to unauthorised or undetectable alteration.</i> <u>Proposed amendments</u> <i>To add –</i> <u>Witnessing and assuring patient and donor identification</u> 8.13 Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. (a) Licensed centres should have <u>witnessing protocols</u> in place to require a second person to counter-check specimen identification and the identities of patients/ husbands/ donors at all critical points of the clinical and laboratory procedures. (b) These checks shall be completed and <u>documented at the time</u> the relevant clinical or laboratory procedure takes place. (c) The date and time of <u>each manipulation</u> and the <u>identity</u> of all operators and witnesses must be documented throughout the treatment. (d) Licensed centres should assign the most appropriate staff to countercheck and counter-sign the clinical and laboratory procedures. (e) Upon completion of two-person witness verification, all specimen containers (including biopsied samples boxes, dry shippers, and fresh/processed semen tubes) must be signed and properly secured with an appropriate tamper-evident seal before being left unattended. Unattended specimens must never remain unsealed.

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7.	Usage and record of training materials	(a) Current provision in the Code only provides general guidelines for centres to observe while using embryos for quality control and training purpose, with its focus mainly on record keeping and lacks detailed guidelines on training materials. (b) Hence, detailed guidelines should be provided on handling, storage and disposal on training and research materials, namely the need for physical separation from materials stored for clinical treatment, maintenance of traceable record and restricted usage of embryos and/or gametes donated for training or research for any clinical treatment service. (c) A transition period of 12 months is proposed to facilitate centres’ compliance with the new requirements on security, inventory checking, anti-misidentification measures, as well as usage and record of training materials (i.e. issues 4-7 of this summary table).	<u>Existing related paragraphs</u> 3.8 A proper and safe storage facility must be provided to preserve the viability of gametes and embryos, to minimise chances of accident, loss or contamination. 10.3 The source of gametes and embryos should be accurately recorded and labelled in a manner which is not susceptible to unauthorised or undetectable alteration. 11.25 In general, the following guiding principles should be observed while using embryos for quality control and training purposes – (a) the number of embryos to be used should be kept to a minimum; (b) use of the embryos must be reasonably incidental to quality control and training purposes; (c) under the direct supervision of embryologist(s) and/or qualified embryology laboratory staff. 14.2 The registers and records required to be kept and maintained by licensed centres are listed at Appendix IX. <u>Appendix IX</u> <u>Records to be Kept and Maintained by Licensed Centres</u> (3) Licensed centres are required to keep and maintain the following records – (d) collection and storage of gametes or embryos at the centre; (e) diagnosis of collected and stored gametes or embryos at the centre; (h) destruction or disposal at the centre of any stored gametes or embryos created in vitro (j) use of gametes or embryos in a RT procedure or research at the centre <u>Proposed amendments</u> To revise – 3.8 A proper and safe storage facility must be provided to preserve the viability of gametes and embryos, to minimise chances of accident, loss or contamination. All gametes and embryos donated for quality control, research or training must be physically separated from materials stored for clinical treatment. The container or tank should be clearly labelled with that the embryo or gamete is unsuitable for clinical use. 10.3 The source of gametes and embryos should be accurately recorded and labelled in a manner which is not susceptible to unauthorised or undetectable alteration. A list of all such cultured

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			and stored gametes and embryos (with proper identification and labels) shall be clearly recorded, regularly updated and readily reproducible for review or audit. <u>General Principles to be Observed for Use of Excess Embryos for Quality Control, Research and Training Purposes</u> 11.25 In general, the following guiding principles should be observed while using embryos for quality control, research and training purposes – (b) use of the embryos must be reasonably incidental to quality control, research and training purposes; and (d) Embryos and/or gametes donated for training or research should not be retained or subsequently used for any clinical treatment service.
8.	Medical Practitioners	(a) In view of the critical importance of ensuring patient safety and upholding robust clinical governance, it is essential to assign an O&G specialist with a minimum of 2 years of post-specialist registration experience in the field of RT, or equivalent experience, as Clinical-in-charge to oversee clinical governance within licensed centres providing clinical service, including treatment centres providing RT clinical services and AIH centres.	<u>Existing related paragraph</u> 2.7 <i>The overall clinical responsibility for RT procedures should be held by registered medical practitioner¹ with relevant training and experience and with post-graduate qualifications recognised by the Hong Kong College of Obstetricians and Gynaecologists or the Hong Kong College of Surgeons, and recognised as an accredited specialist in Obstetrics & Gynaecology, Surgery or Reproductive Medicine under the Specialist Register kept by the Registrar of Medical Practitioners under the Medical Registration Ordinance (Cap. 161). Licensed centres should promptly report to the Council any change(s) of personnel(s) involving <u>medical practitioner(s) and/or person(s) occupying the role of accredited specialist(s)</u>. Centres performing intravaginal or intracervical insemination only are exempted from this requirement.</i> <u>Proposed amendments</u> <i>To add –</i> 2.7A Clinical-in-charge (a) Every licensed centre providing clinical service shall designate a Clinical-in-charge to oversee clinical governance within the centre. The Clinical-in-charge must be a registered medical practitioner who is recognised as an accredited specialist in Obstetrics & Gynaecology under the Specialist Register kept by the Registrar of Medical Practitioners under the Medical Registration Ordinance (Cap. 161); and possesses a minimum of 2 years of post-specialist registration experience in the field of RT, or equivalent experience.

¹ a medical practitioner registered in accordance with s.14 of the Medical Registration Ordinance (Cap. 161)

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			(b) Licensed centres should promptly report to the Council any change(s) of personnel(s) involving Clinical-in-charge.
9.	Person in-charge of a RT laboratory	(a) To ensure the capability and qualification of personnel performing embryology-related procedures, and make sure such procedures are conducted in professional and supervised manner, academic and experience requirement for embryologist-in-charge and embryologist are specified in para. 2.10, 2.11 and Annex VII on the Code. (b) Clinical-in-charge would be responsible for vetting and certifying completion of assisted reproductive cycle of the following – (i) experience of serving embryologist / embryologist-in-charge working at the centre through vetting and certifying of documentation, certifications or past experience in another local centre as appropriate; and (ii) past or foreign experience obtained by the embryologist / embryologist-in-charge to be considered / hired (overseas or local centres) vide vetting and certifying of relevant documentations or certifications deemed appropriate. (c) For course to be attended, courses provided by tertiary institutions or internationally accredited societies/associations, for example, the American Society of Reproductive Medicine (ASRM), the Asia Pacific Initiative on Reproduction (ASPIRE), or the European Society of Human Reproduction and Embryology (ESHRE) were cited as examples for centre’s reference. (d) A transition period of 12 months is proposed to facilitate centres’ compliance with the new requirements on staff in RT laboratory (i.e. both existing and future staff to be recruited).	<u>Existing related paragraph</u> 2.10 <i>The person in-charge of a RT laboratory should have an appropriate scientific or medical degree, plus a period of experience in a RT laboratory sufficient to qualify him/her to take full charge of the laboratory.</i> <u>Proposed amendments</u> <i>To add –</i> 2.10A Embryologist-in-charge (a) A RT laboratory performing embryology-related procedures shall under the professional direction and supervision of an embryologist-in-charge. (b) The embryologist-in-charge shall meet the prescribed academic and experience requirements set out in Annex VII. (c) The person in charge of the RT laboratory under paragraph 2.10 may also serve as the embryologist-in-charge, provided that he/she meets the prescribed requirements for an embryologist-in-charge set out in Annex VII. <u>Annex VII Requirements on embryologist</u> <u>Academic requirements</u> • Bachelor degree or higher in the field of medical or biological sciences <u>Experience requirements</u> • Independent performance of at least 300 assisted reproduction cycles in the course of providing a relevant assisted reproduction service and certified by Clinical-in-charge, such as through a logbook • At least 5 years of independent, practical hands-on experience in carrying out embryology-related procedures with a relevant assisted reproduction service (excluding the 6 months period as an embryologist that requires to work under supervision)

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10.	Scientific or laboratory staff	Ditto	<u>Existing related paragraph</u> <i>2.11 Scientific or laboratory staff should have a degree or higher qualification in a relevant discipline, plus a period of experience sufficient to qualify them to perform the duties of the respective RT procedures. Licensed centres should promptly report to the Council any change(s) of personnel(s) involving person(s) occupying the role of embryologist(s)-in-charge.</i> <u>Proposed amendments</u> <i>To add –</i> 2.11A Embryologists and performance of embryology-related procedures (a) An “embryologist” means a member of scientific or laboratory staff who meets the prescribed academic and experience requirements for embryologists set out in Annex VII, and who is appointed to perform embryology-related procedures. (b) Embryology-related procedures carried out within a licensed RT centre shall be performed only by an embryologist, or by a trainee under the direct and continuous supervision of embryologist-in-charge or embryologists with more than 3 years of experience. (c) Embryology-related procedures include the following: (i) The examination of follicular aspirates; (ii) Oocyte classification; (iii) Sperm preparation for subsequent use in an assisted reproduction procedure or distribution; (iv) Oocyte insemination (whether by IVF or ICSI); (v) Documentation of fertilization and embryo development; and (vi) Preparation of embryos for transfer, including performing of embryo biopsy for testing. <i>To add –</i> <u>Annex VII Requirements for embryologist</u> <u>Academic requirements</u> • Bachelor degree or higher in the field of medical or biological sciences <u>Experience requirements</u> • Has at least 6 months of practical hands-on experience in carrying out the embryology-related procedures under supervision of the embryologist-in-charge or embryologists with more than 3 years of experience • Has satisfactorily performed the laboratory procedures equivalent to at least 50 assisted

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			reproduction cycles under supervision of the embryologist-in-charge or embryologists with more than 3 years of experience • Has attended at least one course on assisted reproduction, such as courses provided by tertiary institutions or internationally accredited societies/associations, for example, the American Society of Reproductive Medicine (ASRM), the Asia Pacific Initiative on Reproduction (ASPIRE), or the European Society of Human Reproduction and Embryology (ESHRE), or others as appropriate. • Has been certified by Clinical-in-charge, such as through a logbook, to possess the competencies required to carry out embryology-related procedures independently without supervision of the embryologist-in-charge or embryologists with more than 3 years of experience

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