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HEALTHCARE SERVICES ACT 2020 (ACT 3 OF 2020)

HEALTHCARE SERVICES (CORD BLOOD BANKING SERVICE) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Healthcare Services (Cord Blood Banking Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

"acute hospital" includes any premises operated by a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use those premises as a private hospital, where the licence specifies that the private hospital is a medical hospital, a surgical hospital or both;

"Clinical Governance Officer" means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;

"cord blood" means the whole blood (including haematopoietic progenitor cells) remaining in placental and umbilical cord blood vessels after an umbilical cord has been clamped;

"incidental finding", in relation to any examination or test of an infant donor or the mother of an infant donor, means any observation, result or other finding about the infant donor or mother (as the case may be) that is disclosed or discovered by or during the examination or test and has potential health or reproductive importance to the infant donor or mother (as the case may be), but is not related to the purpose or objective of the examination or test;

"infant donor" means an infant from whose placenta or umbilical cord any cord blood is obtained;

"licensee" means a person who holds a licence to provide a cord blood banking service;

"medical history", in relation to an individual, includes —

(*a*) information about whether the individual has previously engaged in behaviour that exposes the individual to a high risk of contracting or developing any communicable disease; and

(*b*) information on whether the individual has a history of any genetic disease which may be inherited by a child of the individual;

"mother", in relation to an infant donor, means the woman who carries the infant donor to delivery;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing a cord blood banking service;

"recipient" means an individual to whom cord blood is administered for the purposes of treatment;

"transplant", in relation to cord blood, means the administration of the cord blood to a recipient, whether the recipient is the infant donor of the cord blood, the mother of the infant donor or another individual;

"transplanting clinician", in relation to an acute hospital, means a medical practitioner who is authorised by the acute hospital to transplant cord blood to a recipient.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations, the provisions of these Regulations —

(*a*) apply in addition to the provisions of the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021); and

(*b*) prevail if, and to the extent that, there is any inconsistency between these Regulations and the Healthcare Services (General) Regulations 2021 insofar as the matter relates to an applicable licensee.

Skills and competencies of Clinical Governance Officer

4. For the purposes of section 24(3)(*b*) of the Act, an individual who has all of the following skills and competencies is suitably qualified to be appointed a Clinical Governance Officer for a cord blood banking service:

(*a*) registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(*b*) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of haematology;

(*c*) at least 5 years of work experience in —

(i) haematopoietic stem cell transplant;

(ii) transfusion medicine, provided that the working experience relates to the assessment, screening and evaluation of donors of cord blood;

(iii) blood banking;

(iv) cord blood banking; or

(v) any other activity relating to the provision of a cord blood banking service approved by the Director.

Quality management system

5.—(1) A licensee must establish and maintain an effective quality management system for the cord blood banking service provided by the applicable licensee relating to —

(*a*) the safety of infant donors, the mothers of infant donors and recipients;

(*b*) the safety, quality, potency and viability of cord blood collected, tested, processed, stored and distributed by the licensee; and

(*c*) the proper collection, testing, processing, storage and distribution of cord blood.

(2) The quality management system mentioned in paragraph (1) must provide for all of the following:

(*a*) the investigation of any occurrence or complaint that discloses or may disclose any weakness or inadequacy affecting the quality of the cord blood banking service;

(*b*) the identification and implementation of appropriate and effective actions to address any weakness or inadequacy mentioned in sub-paragraph (*a*) and prevent a recurrence;

(*c*) measures to ensure that the provision of the cord blood banking service complies with the Act, these Regulations and any other regulations made under the Act and any other applicable written law;

(*d*) the implementation of quality control measures for all cord blood collected, tested, processed, stored and distributed by the licensee, including measures pertaining to the safety, quality, potency and viability of the cord blood in relation to —

(i) the recruitment of infant donors and the mothers of infant donors;

(ii) the collection and transport of the cord blood;

(iii) the processing of the cord blood;

(iv) the testing and quarantine of the cord blood; and

(v) the storage and distribution of the cord blood;

(*e*) the implementation of appropriate and effective measures to ensure the safety or health of infant donors and the mothers of infant donors in relation to the collection of cord blood, including the detection and management of any finding or observation that has or may have an adverse effect on the safety or health of the infant donors or mothers;

(*f*) the maintenance of adequate and appropriate documentation on the clinical outcomes of the transplant or other clinical use of all cord blood distributed by the licensee, including documentation relating to any event, finding or observation that —

(i) adversely affects or may adversely affect the safety or health of any recipient; and

(ii) relates to or is the result of the collection, testing, processing, storage or distribution of cord blood by the licensee;

(*g*) quality control measures for tests performed and equipment used in the provision of the cord blood banking service, including acceptance testing, quality control tests and regular monitoring of equipment performance;

(*h*) a system to ensure the appropriate and adequate documentation of the licensee's policies and processes, including —

(i) creating, reviewing and updating documentation for the licensee's quality assurance measures and all personnel's compliance with those measures; and

(ii) ensuring proper document control of all such documentation;

(*i*) regular participation in relevant external quality assessment programmes for each test performed for product qualification;

(*j*) the review of the results of the external quality assessment programmes mentioned in sub-paragraph (*i*) by a Clinical Governance Officer or a suitably qualified individual designated by a Clinical Governance Officer;

(*k*) the implementation of a system for appropriate accountability, roles and responsibilities of and continuing educational programmes for all personnel;

(*l*) identification of key performance indicators for assessing performance outcomes of the cord blood banking service, including mechanisms for periodic monitoring and evaluation of these indicators;

(*m*) the conduct of regular risk assessments of every activity conducted as part of the provision of the cord blood banking service and, where necessary, the implementation of appropriate measures to mitigate or manage the risks identified in those assessments.

(3) A licensee must —

(*a*) conduct regular reviews of the quality management system mentioned in paragraph (1);

(*b*) make and maintain accurate reports of all reviews conducted under sub-paragraph (*a*); and

(*c*) update the quality management system as may be necessary, including in response to the findings of any review conducted under sub-paragraph (*a*).

(4) A second or subsequent review of the quality management system mentioned in paragraph (1) must be conducted during the twelfth month after the month in which the licensee conducted the immediately preceding review.

Personnel involved in providing cord blood banking service

6.—(1) A licensee must appoint —

(*a*) a suitably qualified individual as the licensee's Laboratory Director;

(*b*) a suitably qualified individual as the licensee's Medical Director; and

(*c*) one or more individuals who have relevant qualifications or training in quality management as the licensee's quality personnel.

(2) A licensee must ensure that any personnel who has less than 2 years of relevant experience must not perform any task or provide

any service in relation to the provision of the cord blood banking service except under the close supervision of —

(*a*) a Clinical Governance Officer; or

(*b*) another personnel with at least 2 years of relevant work experience and who is designated by a Clinical Governance Officer to provide supervision.

(3) A licensee must ensure that —

(*a*) each personnel is adequately trained for the work performed by that personnel and attends regular training in accordance with a continuing training programme;

(*b*) each personnel has the relevant awareness and knowledge of, and attends regular training on, measures to ensure the safe provision of the cord blood banking service;

(*c*) the competencies of each personnel are assessed before that personnel is allowed to perform any task or provide any service in relation to the licensee's provision of the cord blood banking service; and

(*d*) the work performance of each personnel is assessed periodically.

(4) In paragraph (2), "relevant experience" of a personnel means the work experience of that personnel relevant to the tasks performed and services provided by that personnel in relation to the provision of a cord blood banking service.

Quality personnel

7.—(1) The duties of the quality personnel of a licensee are —

(*a*) to maintain the quality management system mentioned in regulation 5(1) and any related system, and any other quality system established by a Clinical Governance Officer; and

(*b*) to review, manage, approve and implement policies and procedures relating to the quality of the cord blood banking service.

(2) The quality personnel must report any findings relating to the safety of the cord blood banking service or the safety, quality, potency and viability of any cord blood collected, tested, processed, stored or distributed by the licensee to the Principal Officer of the licensee in a timely manner.

(3) The licensee, the Principal Officer and a Clinical Governance Officer must not impede or influence, or attempt to impede or influence, any quality personnel in the discharge of that individual's duties under this regulation.

Facilities, equipment, supplies, etc.

8.—(1) A licensee must ensure that every licensed premises is safe, secure, appropriate and adequate for the provision of the cord blood banking service.

(2) Without limiting paragraph (1), the licensee must ensure all of the following:

(*a*) access to the licensed premises is restricted to individuals authorised by a Clinical Governance Officer;

(*b*) the instruments and other equipment used or to be used in relation to the provision of the cord blood banking service are properly installed and commissioned for use;

(*c*) every refrigerator or storage tank undergoes periodic maintenance to ensure the quality and usability of cord blood and reagents kept in the refrigerator or storage tank;

(*d*) all refrigerators and storage tanks are used in a manner that —

(i) prevents the mix-up, or contamination or cross-contamination, of units of cord blood; and

(ii) ensures the safety, quality, viability and potency of cord blood;

(*e*) all instruments and other equipment, supplies and reagents used in the provision of the cord blood banking service are effective to ensure the safety, quality, viability and potency of cord blood;

(*f*) a procedure is put in place for monitoring, inspecting, sterilising and cleaning each piece of equipment used in the provision of the cord blood banking service;

(*g*) appropriate tests and procedures are carried out periodically to ensure that any equipment or reagent used in the provision of the cord blood banking service complies with at least the tolerance limits determined by the manufacturer of the equipment or reagent;

(*h*) the suppliers of any materials, the use of which is likely to have a material impact on the safety, quality, viability or potency of cord blood, are selected and regularly evaluated to ensure that the materials obtained from the suppliers are safe and effective;

(*i*) the following information about any supplies or reagent used in the collection, testing, processing and storage of cord blood by the licensee is identified and recorded:

(i) the name of the supplies or reagent;

(ii) the name of the manufacturer;

(iii) the lot number;

(iv) the expiration date;

(*j*) all sterilised instruments, supplies and reagents are clearly labelled to indicate the date on which the sterilisation took place and the expiry date of the sterilisation;

(*k*) procedures are put in place to monitor and maintain the conditions in which cord blood is stored, including the immediate notification of and response to temperature deviations outside acceptable ranges;

(*l*) adequate, stable and appropriate electricity supply is provided for all laboratory equipment, including an adequate number of grounded electrical outlets and an emergency power supply for each piece of equipment that is essential for maintaining the safety, quality, viability and potency of cord blood;

(*m*) safety procedures are developed and implemented.

Consent for donation and pre-donation counselling

9.—(1) For the purposes of the donation of the cord blood of an infant donor, a licensee must obtain prior express written consent from the mother of the infant donor for all of the following before the mother is in active labour:

(*a*) the donation of cord blood of the infant donor;

(*b*) the collection and storage of any cord blood of the infant donor.

(2) A licensee must, before obtaining the mother's consent under paragraph (1), provide adequate and appropriate counselling to the mother.

(3) A licensee must ensure that—

(*a*) the counselling mentioned in paragraph (2) is conducted by one or more competent personnel who has appropriate qualifications or training; and

(*b*) adequate records of the counselling provided are maintained.

(4) A licensee must, at the time the mother's consent under paragraph (1) is sought —

(*a*) inform the mother of all of the following:

(i) the purposes for which the cord blood collected is to be used;

(ii) any tests necessary to assess the suitability of the cord blood for use;

(iii) where the cord blood is found to be of low potency or contaminated — the manner in which the licensee will deal with the cord blood;

(iv) where the cord blood is distributed for the purpose of transplant — that the licensee will disclose to the acute hospital to which the cord blood is distributed (including the transplanting clinician who transplants or will transplant the cord blood) the following information:

(A) the medical history of the infant donor of the cord blood and the mother;

(B) information relating to the licensee's testing and processing of the cord blood; and

(*b*) ascertain whether the mother, in the event of any abnormal finding or incidental finding relating to the infant donor or mother, consents to either or both of the following:

(i) the infant donor or mother being re-identified by the licensee and informed of the abnormal finding or incidental finding;

(ii) the medical practitioner caring for the infant donor or mother (as the case may be) being informed of the abnormal finding or incidental finding.

(5) A licensee must ensure that —

(*a*) the mother is given sufficient time, after receiving the counselling mentioned in paragraph (2), to decide whether or not to give her consent under paragraph (1); and

(*b*) the mother's consent under paragraph (1) is not obtained by means of coercion, intimidation, deception or misrepresentation by any officer, employee or agent of the licensee.

(6) This regulation applies in addition to and does not affect any requirement, restriction or prohibition under any other written law or rule of law.

Evaluation and screening

10.—(1) A licensee must implement a system for evaluating the medical fitness and suitability of every infant donor and mother of an infant donor (including a potential infant donor and the mother of a potential infant donor).

(2) Without limiting paragraph (1), the licensee must, in relation to the mother of every potential infant donor —

(*a*) ensure that a medical practitioner reviews the clinical history, and conducts a clinical evaluation, of the mother; and

(*b*) obtain a declaration signed by the mother that contains, to the best of the knowledge of the mother at the time she makes the declaration, information relating to the matters specified in paragraph (3).

(3) The matters mentioned in paragraph (2)(*b*) are the following:

(*a*) the medical history of the mother of the potential infant donor and every member of her immediate family;

(*b*) where the father of a potential infant donor is not the spouse of the mother — the medical history of the father;

(*c*) the medical history of every member of the immediate family of the father of the potential infant donor;

(*d*) where the mother is bearing a potential infant donor conceived using a donated egg or donated sperm — the medical history of the donor of the egg or sperm and every member of that donor's immediate family.

(4) Without limiting paragraph (1), the licensee must ensure that the system mentioned in that paragraph provides for all of the following:

(*a*) the collection, from the time the licensee obtains a declaration mentioned in paragraph (2)(*b*) until the time the mother of an infant donor delivers the infant donor, of any information relating to the matters specified in paragraph (3) that is known or available to the licensee;

(*b*) the communication to the mother of the infant donor and (where the mother consents) the medical practitioner caring for the mother of —

(i) any abnormal finding that may have significant consequences for the health or fertility of the infant donor or mother; or

(ii) any incidental finding relating to the infant donor or mother.

(5) A licensee must ensure that —

(*a*) the mother of an infant donor, in relation to an infectious disease specified in the first column of the Schedule, has undergone all of the tests specified opposite that infectious disease in the second column of the Schedule; and

(*b*) every test of the mother of an infant donor carried out in accordance with sub-paragraph (*a*) is carried out using appropriate test kits that have been validated for the purpose of donor testing.

(6) A licensee must, in order to enable the conduct of any subsequent testing of the cord blood collected from an infant donor that may be necessary —

(*a*) collect —

(i) a sufficient quantity of cord blood in addition to the cord blood collected for transplant or other clinical use; and

(ii) blood samples of the mother of the infant donor; and

(*b*) ensure that the cord blood and blood samples mentioned in sub-paragraph (*a*) are stored and available for any subsequent testing that may be necessary for the duration of the contract or other arrangement between the licensee and the mother of the infant donor for the collection and storage of the cord blood collected.

(7) In this regulation, "immediate family", in relation to an individual, means the individual's spouse, son, adopted son, stepson, daughter, adopted daughter, stepdaughter, father, stepfather, mother, stepmother, brother, stepbrother, sister or stepsister.

Testing of infant donor or mother of infant donor

11. Where a licensee requires an infant donor or the mother of an infant donor to undergo any test in relation to the licensee's provision of a cord blood banking service, the licensee must —

(*a*) ensure that the test is conducted only by —

(i) a person who is authorised by a licence under the Act to provide a clinical laboratory service or blood banking service; or

(ii) a person who operates a clinical laboratory or blood bank outside Singapore who is accredited by an accreditation body acceptable to the Director; and

(*b*) retain a copy of the test report provided by the person who conducted the test.

Collection of cord blood

12. A licensee must, in relation to the collection of cord blood —

(*a*) develop appropriate protocols for the safe and proper collection of cord blood;

(*b*) ensure that each individual who collects cord blood for or on behalf of the licensee is trained and competent in the protocols mentioned in paragraph (*a*); and

(*c*) provide all equipment and materials necessary for the safe and proper collection of the cord blood.

Processing, testing and quarantine of cord blood

13.—(1) A licensee must —

(*a*) implement appropriate and adequate processes for the processing, testing and quarantine of all cord blood in the possession or custody of the licensee in order to ensure the safety, quality, viability and potency of the cord blood for transplant or other clinical use; and

(*b*) determine and implement all tests for the cord blood that may be necessary.

(2) Without limiting paragraph (1), the licensee must, in relation to the processing, testing and quarantine of cord blood, satisfy all of the following requirements:

(*a*) the licensee must develop and implement written policies and procedures for the processing, testing and quarantine

of cord blood, and ensure that all cord blood collected is processed, tested and quarantined in accordance with those policies and procedures;

(*b*) the environment within which the cord blood is processed, tested and quarantined must be appropriate to ensure the safety, quality, viability and potency of the cord blood, and the safety of all personnel handling the cord blood;

(*c*) the cord blood is collected and cryopreserved within the appropriate time period for the cord blood to retain the biological functions compatible with its intended use;

(*d*) the cord blood collected from an infant donor is not mixed together with the cord blood collected from any other infant donor;

(*e*) the licensee must take all reasonable steps to minimise the risk of contamination of the cord blood;

(*f*) validated methods and appropriate protocols for the processing (including cryopreservation) and testing of cord blood are used to maintain the safety, quality, viability and potency of the cord blood and retain the therapeutic properties of the cord blood which are consistent with its intended use;

(*g*) the licensee must establish and validate the time period within which the processing and testing of cord blood has to be completed with an acceptable product end point;

(*h*) the licensee must maintain the traceability of all materials and equipment used to process the cord blood.

(3) Without limiting paragraph (1), the licensee must, in relation to the testing of cord blood, satisfy all of the following requirements:

(*a*) the licensee must establish written criteria and procedures for the evaluation and assessment of the quality of cord blood;

(*b*) the licensee must implement appropriate tests and procedures for measuring and assaying cord blood to determine its safety, quality, viability and potency;

(*c*) the licensee must, before cryopreserving the cord blood —

(i) obtain representative microbiological cultures of the cord blood; and

(ii) test the representative microbiological cultures for bacteria or fungi;

(*d*) the licensee must determine the potency of the cord blood —

(i) before cryopreserving the cord blood; and

(ii) before distributing the cord blood for transplant or other clinical use;

(*e*) the licensee must conduct Human Leukocyte Antigen typing of the cord blood;

(*f*) the licensee must record, in the licensee's record relating to the infant donor of the cord blood, the test results and information relating to the matters in sub-paragraphs (*c*), (*d*) and (*e*);

(*g*) the licensee must, where any pathogen is found in any cord blood that renders the cord blood unsuitable for clinical use, discard the cord blood using an appropriate sterilising procedure that has been validated to eliminate the infectivity of the pathogen;

(*h*) a Clinical Governance Officer or any personnel designated by a Clinical Governance Officer must, before the licensee distributes any cord blood for transplant or other clinical use, review —

(i) the results of any representative microbiological culture performed on the cord blood, including any variance from the applicable standard for microbiological cultures determined by a Clinical Governance Officer; and

(ii) the results of the tests conducted on the infant donor of the cord blood and the mother of that infant donor, including any variance from the applicable standard for determining the suitability of the cord blood for

recipients determined by a Clinical Governance Officer.

(4) Without limiting paragraph (1), the licensee must, in relation to the quarantine of cord blood, satisfy all of the following requirements:

(*a*) the cord blood must be quarantined while it is being processed or tested in accordance with the licensee's written policies and procedures where the safety, quality, viability or potency of the cord blood may be affected by its release into the licensee's inventory;

(*b*) any cord blood that has been quarantined must not be released into the licensee's inventory or distributed to any other person except in accordance with the licensee's written criteria and procedures and with the approval of a Clinical Governance Officer.

Suitability of recipient of cord blood

14.—(1) A licensee must, in relation to the distribution of any cord blood for transplant or other clinical use, evaluate whether the cord blood is suitable —

(*a*) for transplant or other clinical use generally; and

(*b*) for transplant to or other clinical use by the proposed recipient of the cord blood.

(2) Where a licensee is aware of any adverse reaction in relation to the transplant or other clinical use of any cord blood provided by the licensee, a Clinical Governance Officer must review all available information about the adverse reaction to identify and remedy any errors, inadequacies or shortcomings in relation to the licensee's provision of the cord blood banking service.

Storage of cord blood

15.—(1) A licensee must establish and implement an inventory management system that ensures that —

(*a*) the biological and functional properties of all cord blood in the licensee's custody are preserved; and

(*b*) the risk of contamination of the cord blood is minimised.

(2) Without limiting paragraph (1), the licensee must, in relation to the storage and inventory management of the cord blood in its custody, satisfy all of the following requirements:

(*a*) the cord blood must be stored in a validated container that is appropriate for its intended use;

(*b*) every unit of cord blood must be packaged appropriately;

(*c*) the licensee must maintain and periodically audit the licensee's inventory system for the cord blood in the licensee's custody, including all cord blood under quarantine;

(*d*) the licensee must implement an appropriate labelling system to ensure that every unit of cord blood is correctly identified and traceable from the time of its collection until the time it is distributed;

(*e*) all cord blood that has been tested and processed must be stored at an appropriate temperature;

(*f*) the storage requirements (including storage conditions and expiry date) for the cord blood must be appropriate, having regard to —

(i) the packaging and processing requirements for cord blood; and

(ii) the intended use of cord blood;

(*g*) the maximum storage period of the cord blood must be appropriate, having regard to —

(i) the appropriate storage temperature for cord blood;

(ii) the packaging and processing requirements for cord blood; and

(iii) the intended use of cord blood;

(*h*) any cord blood that is under quarantine must be clearly labelled and segregated from any cord blood intended for distribution;

(*i*) where any unit of cord blood is determined to be unsuitable for transplant or other clinical use, the unit of cord blood must be clearly labelled with all of the following:

(i) that the unit of cord blood is unsuitable for transplant or other clinical use;

(ii) the purpose for which the unit of cord blood may be distributed, if any.

Distribution of cord blood

16.—(1) A licensee must ensure that the distribution of cord blood is carried out such that —

(*a*) the biological and functional properties of the cord blood are preserved; and

(*b*) the risk of contamination of the cord blood is minimised.

(2) Without limiting paragraph (1), the licensee must satisfy all of the following requirements:

(*a*) the cord blood must be packaged and transported in a validated container;

(*b*) the licensee must implement and maintain a system to prevent or control the spread of any communicable disease due to the contamination or infection of any cord blood in the licensee's custody, including the traceability of all equipment and materials used in the processing of the cord blood;

(*c*) the cord blood is distributed in appropriate conditions, including the storage of the cord blood during transport and the thawing of the cord blood before use;

(*d*) the licensee must establish and implement written policies and procedures, where the suitability of any unit of cord blood for its intended use is or is believed to have been adversely affected for any reason (such as possible contamination or defects in the processing, testing or preparation of that unit of cord blood), for —

(i) the recall of the unit of cord blood; and

(ii) the notification of any person who receives or has received the unit of cord blood;

(*e*) an instruction sheet which includes all of the following information must accompany every unit of cord blood distributed by the licensee:

(i) the results of all screenings of the infant donor of the cord blood and the mother of that infant donor;

(ii) the appropriate storage conditions for the cord blood prior to its transplant or other clinical use;

(iii) any special requirement or measure that the medical practitioner using the cord blood must take to ensure the safe and effective use of the cord blood;

(iv) the measures that must be taken if there is any evidence of damage to or mislabelling of the cord blood or its packaging.

(3) A licensee —

(*a*) subject to paragraphs (4) and (5), must distribute any unit of cord blood only for a purpose for which the mother of the infant donor from whom that unit of cord blood was collected has given express written consent; and

(*b*) must not distribute any unit of cord blood for any purpose except with the approval of a Clinical Governance Officer.

(4) A licensee must not distribute any unit of cord blood for the purpose of transplant except to an acute hospital.

(5) Where any unit of cord blood is determined to be unsuitable for transplant or other clinical use, the licensee must ensure that the unit of cord blood is distributed in accordance with the requirements of these Regulations and other applicable written law.

Distribution of cord blood on exceptional grounds where infant donor or mother of infant donor suffers from infectious diseases

17.—(1) This regulation applies where a licensee determines that an infant donor or the mother of an infant donor is suffering from any infectious disease mentioned in the first column of the Schedule or any other infectious disease as a Clinical Governance Officer may determine.

(2) The licensee may distribute any cord blood collected from an infant donor mentioned in paragraph (1) (called in this regulation the applicable cord blood) for the purpose of transplant only with the approval of a Clinical Governance Officer.

(3) A Clinical Governance Officer may approve the distribution of any applicable cord blood under paragraph (2) only if the Clinical Governance Officer is satisfied that —

(*a*) there is clinical indication for the applicable cord blood to be used for that purpose; and

(*b*) having regard to the particular circumstances, there is medical urgency to use the applicable cord blood.

(4) Where any applicable cord blood is distributed in accordance with paragraph (2), the applicable licensee must ensure that appropriate infection control measures are taken.

Import of cord blood

18. A licensee may, in relation to the provision of a cord blood banking service, import cord blood supplied by a person outside Singapore only if that person is accredited by an accreditation body acceptable to the Director.

Re-identification and notification of infant donor and mother of infant donor — abnormal findings or incidental findings

19. A licensee must establish and implement a process for all of the following:

(*a*) determining whether the mother of an infant donor consents to either or both of the following:

(i) the infant donor or mother being re-identified and informed of any abnormal finding or incidental finding relating to any cord blood collected from the infant donor;

(ii) the medical practitioner caring for the infant donor or mother (as the case may be) being informed of any such abnormal finding or incidental finding;

(*b*) where the mother gives express written consent for the matter specified in paragraph (*a*)(i) —

(i) re-identifying the infant donor or mother, as the case may be; and

(ii) informing the mother of the abnormal finding or incidental finding;

(*c*) where the mother gives express written consent for the matter specified in paragraph (*a*)(ii) —

(i) re-identifying the infant donor or mother, as the case may be; and

(ii) informing the medical practitioner of the abnormal finding or incidental finding.

Collection of information about infant donor and mother of infant donor

20. A licensee must —

(*a*) collect all information that ensures the linkage of all cord blood units collected from an infant donor and the mother of that infant donor;

(*b*) take all reasonable steps to ensure the confidentiality and security of all information mentioned in paragraph (*a*); and

(*c*) keep and maintain accurate records of all information mentioned in paragraph (*a*) indefinitely.

Records

21.—(1) A licensee must —

(*a*) keep and maintain complete and accurate records of the licensee's policies, procedures and programmes in relation to the cord blood banking service;

(*b*) ensure proper document control of all documents relating to the cord blood banking service; and

(*c*) take all reasonable steps to ensure the confidentiality and security of all records mentioned in sub-paragraph (*a*).

(2) Without limiting paragraph (1), the licensee must ensure that all of the following requirements are satisfied:

(*a*) the licensee must establish and implement a process to ensure proper document control of all documents relating to the cord blood banking service by one or more appropriate personnel;

(*b*) the licensee's procedures and practices for the cord blood banking service must be set out in one or more procedure manuals;

(*c*) a Clinical Governance Officer must approve, sign and date each procedure manual mentioned in sub-paragraph (*b*);

(*d*) the procedure manuals mentioned in sub-paragraph (*b*) must be made available at all times to all personnel and regularly updated;

(*e*) accurate records must be kept and maintained of the time at which every unit of cord blood is accepted into the processing facility of the licensed premises;

(*f*) where any cord blood is to be transferred to another licensee or a person outside Singapore that is licensed, registered, approved or otherwise allowed to carry on the activities of a cord blood bank under the laws of the foreign jurisdiction — there must be a written agreement setting out the terms of the transfer of the cord blood;

(*g*) the licensee must document and validate any change to the licensee's procedures or processes or any equipment or system used in relation to the provision of the cord blood banking service before the change is implemented.

(3) The licensee must keep and maintain complete and accurate records of the approval given by a Clinical Governance Officer under regulation 16(3)(*b*) or 17(2) for the distribution of every unit of cord blood.

Provision of information relating to cord blood distributed for transplant

22.—(1) This regulation applies to a licensee in relation to any unit of cord blood distributed by the licensee to an acute hospital for the purpose of transplant.

(2) The licensee must, in relation to the unit of cord blood distributed, provide the results of the following to the acute hospital (including the transplanting clinician who transplants or intends to transplant the cord blood):

(*a*) all screenings of the infant donor of the cord blood and the mother of that infant donor;

(*b*) all tests conducted of the cord blood.

(3) The licensee must, upon request by the acute hospital or the transplanting clinician, make available the following information to the acute hospital or transplanting clinician (as the case may be):

(*a*) the medical history of the infant donor from whom the unit of cord blood was collected and the mother of that infant donor;

(*b*) information relating to the licensee's testing and processing of the unit of cord blood.

(4) The licensee must obtain from the transplanting clinician, within such time as a Clinical Governance Officer considers appropriate after the transplant has taken place, the following information:

(*a*) information concerning any adverse reaction arising from the transplant of the cord blood;

(*b*) information about the recipient of the cord blood.

(5) This regulation is subject to any prohibition or restriction under any other written law or rule of law.

Continuity of operations

23.—(1) A licensee must establish a contingency plan to ensure that the safety, quality, viability and potency of all cord blood in the licensee's custody are preserved in the event of any disruption to the licensee's operations.

(2) Without limiting paragraph (1), the contingency plan mentioned in that paragraph must include the following matters:

(*a*) contracts or other arrangements for or in relation to the prompt restoration of the licensee's operations or the transfer of cord blood in the licensee's custody to another licensee;

(*b*) processes —

(i) to inform, without undue delay, a relevant person of the proposed transfer or disposal of any cord blood collected from an infant donor as a result of the disruption to the licensee's operations; and

(ii) to obtain the express written consent of the relevant person for the proposed transfer or disposal.

(3) In paragraph (2)(*b*), "relevant person" means either of the following individuals:

(*a*) the mother of an infant donor, unless sub-paragraph (*b*) applies;

(*b*) an infant donor, where —

(i) the licensee intends to transfer or dispose of any cord blood collected from the infant donor; and

(ii) the infant donor has, at the time of the proposed transfer or disposal, attained the age of majority.

Outsourcing

24.—(1) Except as provided in this regulation, a licensee must not appoint any person to provide, on the licensee's behalf, a cord blood banking service or any aspect of the cord blood banking service.

(2) A licensee may appoint any of the following persons to conduct, on the licensee's behalf, any test of any cord blood that the licensee considers necessary to ensure the safety, quality, viability and potency of the cord blood:

(*a*) another licensee;

(*b*) a person who is authorised by a licence to provide a clinical laboratory service;

(*c*) a person who operates a cord blood bank or clinical laboratory outside Singapore that is accredited by an accreditation body acceptable to the Director.

(3) Where a licensee has engaged a person under paragraph (2) to conduct any test of any cord blood, the licensee must retain a copy of the test report provided by that person.

(4) A licensee may, for or in relation to the implementation of a contingency plan mentioned in regulation 23(1), engage any person to process, store or distribute any cord blood on the licensee's behalf.

(5) To avoid doubt, a licensee who appoints another person to carry on any activity under paragraph (2) or (4) remains responsible to comply with the licence conditions imposed on and the duties of a licensee under the Act, these Regulations and any other regulations made under the Act.

Price transparency

25. A licensee must, before providing the cord blood banking service to the mother of an infant donor —

(*a*) inform the mother of all applicable charges (including administrative charges) relating to the provision of the cord blood banking service; and

(*b*) obtain the mother's express written agreement to the applicable charges mentioned in paragraph (*a*).

Offence

26.—(1) Any person who contravenes regulation 5, 8(1), 9(5), 10(1), (5) or (6), 11, 12, 13(1), 14(1) or (2), 15(1), 16(1), (3) or (4), 17(2) or (4), 18, 19, 20, 21(1) or (3), 22(2), (3) or (4), 23(1) or 24(1) or (3) shall be guilty of an offence.

(2) A person who is guilty of an offence under paragraph (1) shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding $1,000 for every day or part of a day during which the offence continues after conviction.

THE SCHEDULE

Regulations 10(5) and 17(1)

INFECTIOUS DISEASES FOR WHICH MOTHER OF INFANT DONOR TO BE TESTED

First column	*Second column*
1. Cytomegalovirus	(*a*) serology
2. Hepatitis B infection	(*a*) serology
	(*b*) nucleic acid test
3. Hepatitis C infection	(*a*) serology
	(*b*) nucleic acid test
4. Human immunodeficiency virus (HIV) infection	(*a*) serology
	(*b*) nucleic acid test
5. Human T-cell lymphotropic virus types I and II	(*a*) serology
6. Syphilis	(*a*) serology

Made on 27 December 2021.

CHAN YENG KIT
Permanent Secretary,
Ministry of Health,
Singapore.

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