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HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (HUMAN TISSUE BANKING SERVICE) REGULATIONS 2023

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

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Healthcare Services (Human Tissue Banking Service) Regulations 2023 and come into operation on 26 June 2023.

Definitions

2. In these Regulations —

"authorised person", in relation to a deceased donor, means the person who may give all or any part of the body of the deceased donor under section 4 of the Medical (Therapy, Education and Research) Act 1972;

"collect", in relation to any human tissue, means to remove the human tissue from the body of a donor;

"donor" means an individual, whether living or deceased, from whose body any human tissue is removed for the purposes of transplant or other clinical use;

"General Regulations" means the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021);

"incidental finding", in relation to any examination or test on any human tissue collected from a donor, means any observation, result or other finding about the donor that is disclosed or discovered by or during the examination or test and has potential health or reproductive importance to the donor, but is not related to the purpose or objective of the examination or test;

"licensee" means a person who holds a licence to provide a human tissue banking service;

"living donor", in relation to any human tissue, means a donor who is alive when the human tissue is removed from the donor;

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

"recipient", in relation to any human tissue transplanted or used for the purpose of treating or preventing a human disease, means an individual to whose body the human tissue is transplanted or in whose body the human tissue is used;

"transplant", in relation to any human tissue, means —

(*a*) to remove the human tissue from any part of the body of the donor; and

(*b*) to transfer the human tissue to —

(i) the donor's body, whether it is the same part of the donor's body from which the human tissue was removed or another part of the donor's body; or

(ii) the body of any other individual,

whether or not the human tissue is processed, altered or manipulated after its removal from the donor's body;

"transplanting clinician", in relation to any human tissue, means the medical practitioner who carries out the transplant of the human tissue;

"transplanting licensee", in relation to any human tissue, means a person who holds a licence to provide an acute hospital service or ambulatory surgical centre service and performs or intends to perform a transplant of the human tissue;

"validated container", in relation to the storage of any human tissue, means a container that is validated to store the human tissue in the conditions that will ensure that the human tissue will remain appropriate for its intended use.

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 General Regulations; and

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

Specified services

4. For the purposes of section 9A(1) of the Act, the services set out in the First Schedule are specified services for a human tissue banking service.

Notification of handling, processing, etc., of additional types of human tissue

5. A licensee that intends to handle, process, test, store or distribute any type of human tissue that is not set out in the First Schedule must give the Director-General written notice of the licensee's intention no later than 2 months before the licensee intends to start handling, processing, testing, storing or distributing that type of human tissue.

Prohibited service delivery modes

6. A licensee must not provide a human tissue banking service using any of the following service delivery modes:

(*a*) any premises other than permanent premises;

(*b*) using a conveyance;

(*c*) by remote provision.

PART 2

REQUIREMENTS RELATING TO PERSONNEL AND PROCESSES

Qualifications, skills and competencies of Clinical Governance Officer

7. For the purposes of section 24(3)(*b*) of the Act, an individual is suitably qualified to be appointed a Clinical Governance Officer for a human tissue banking service if the individual —

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

(*b*) holds a valid practising certificate under the Medical Registration Act 1997;

(*c*) is registered under section 22 of the Medical Registration Act 1997 as a specialist in any branch of medicine; and

(*d*) has at least 5 years of work experience in providing a human tissue banking service, blood banking or cord blood banking service.

Appointment of advising specialist

8. Where —

(*a*) a licensee is approved to provide a specified service; and

(*b*) the Clinical Governance Officer appointed by the licensee is not, or none of the Clinical Governance Officers appointed by the licensee is, registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of medicine relevant to the specified service,

the licensee must appoint a medical practitioner who is so registered as a specialist in the branch of medicine relevant to the specified service to advise the licensee's Clinical Governance Officer or Clinical Governance Officers on the clinical aspects of the specified service.

General requirements relating to personnel

9.—(1) A licensee must ensure all of the following in relation to each personnel:

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

(*b*) each personnel is assessed periodically on the personnel's competencies and work performance;

(*c*) each of the following personnel is supervised by an experienced person when performing any task or providing any service in relation to a specified service that the licensee is approved to provide:

(i) any personnel with less than 2 years of work experience in performing that task or providing that service;

(ii) any personnel who has not been assessed by an experienced person to be able to perform the task or provide the service competently without supervision.

(2) In this regulation, "experienced person" means —

(*a*) a Clinical Governance Officer; or

(*b*) another of the licensee's personnel with at least 5 years of relevant work experience in providing the specified service and who is designated by a Clinical Governance Officer to provide supervision.

Quality management system

10.—(1) A licensee must establish and implement a quality management system in accordance with this regulation for the purposes of quality assessment and assurance of the human tissue banking service, in relation to the following:

(*a*) the safety of donors and recipients;

(*b*) the safety and quality, and, where applicable, the viability and potency, of human tissue collected, tested, processed, stored and distributed by the licensee;

(*c*) the proper collection, testing, processing, storage and distribution of human tissue.

(2) Without limiting paragraph (1), the quality management system mentioned in that paragraph must provide for all of the following:

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

(*b*) 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 human tissue banking service complies with any written law governing the service and licence conditions imposed under section 13(1) of the Act;

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

(i) where the licensee recruits donors — the recruitment of donors;

(ii) the collection and transport of the human tissue;

(iii) the processing (including testing and quarantine) of the human tissue; and

(iv) the preservation, storage and distribution of the human tissue;

(*e*) implementation of appropriate and effective measures to ensure the safety or health of donors in relation to the collection of human tissue, 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 donors;

(*f*) maintenance of adequate and appropriate documentation on the clinical outcomes of the transplant or other clinical use of all human tissue 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 human tissue by the licensee;

(*g*) quality control measures for tests performed and equipment used in the provision of the human tissue 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*) implementation of a system for appropriate accountability, roles and responsibilities of and continuing educational programmes for all personnel;

(*j*) identification of key performance indicators for assessing performance outcomes of the human tissue banking service, including mechanisms for periodic monitoring and evaluation of these indicators;

(*k*) the conduct of regular risk assessments of every activity conducted as part of the provision of the human tissue 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*) review the effectiveness of the quality management system for the human tissue banking service on an annual basis; and

(*b*) ensure that the quality management system is updated periodically.

(4) In addition, a licensee must —

(*a*) participate in and perform satisfactorily for the relevant external quality assessment programme for every type of test that the licensee conducts on human tissue as part of the human tissue banking service; and

(*b*) ensure that a Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer reviews the results of the quality assessment programmes mentioned in sub-paragraph (*a*) and implements appropriate and effective actions to address any weakness or inadequacy in the provision of the human tissue banking service.

PART 3

PREMISES AND EQUIPMENT

Requirements relating to permanent premises

11.—(1) A licensee must ensure that every approved permanent premises is —

(*a*) safe and secure; and

(*b*) set up in a manner that is appropriate and adequate for the provision of the human tissue banking service.

(2) Without limiting paragraph (1), the licensee must ensure that access to any part of the approved permanent premises in which any human tissue is stored is restricted to individuals authorised by a

Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer.

Requirements relating to equipment and materials

12.—(1) A licensee must ensure that —

(*a*) the equipment and materials used or intended to be used in the provision of the human tissue banking service are safe for such use; and

(*b*) the equipment and materials are used in a manner that ensures the safe provision of the human tissue banking service.

(2) Without limiting paragraph (1), a licensee must ensure that —

(*a*) each instrument and each equipment is installed, commissioned and used or operated properly, in accordance with the instructions of the manufacturer of the instrument or equipment;

(*b*) every refrigerator or storage tank undergoes periodic maintenance to ensure the quality and usability of human tissue and reagents kept in the refrigerator or storage tank;

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

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

(ii) ensures the safety and quality, and, where applicable, the viability and potency, of human tissue;

(*d*) all instruments and other equipment, supplies and reagents used in the provision of the human tissue banking service are effective to ensure the safety and quality, and, where applicable, the viability and potency, of human tissue;

(*e*) procedures are implemented for monitoring, inspecting and sterilising or cleaning each equipment used in the provision of the human tissue banking service;

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

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

(*h*) the following information about any supplies or reagent used in the collection, testing, processing and storage of human tissue 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 expiry date;

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

(*j*) procedures are implemented to monitor and maintain the conditions in which human tissue is stored, including the immediate notification of and response to temperature deviations outside acceptable ranges;

(*k*) 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 and quality, and, where applicable, the viability and potency, of human tissue; and

(*l*) procedures are implemented to ensure the safety of personnel using all facilities and equipment for the human tissue banking service.

PART 4

SAFETY REQUIREMENTS

Safety programme

13.—(1) A licensee must develop and implement a safety programme setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident and reduce any hazard at each of the licensee's approved permanent premises.

(2) Without limiting paragraph (1), a safety programme must contain appropriate and effective measures for —

(*a*) electrical safety and safety of water supply and outlets;

(*b*) the handling and disposal of sharp apparatus and objects that can readily puncture or cut human skin when encountered;

(*c*) the safety of all personnel and donors during the conduct of any test;

(*d*) waste management;

(*e*) spills management;

(*f*) ensuring that there is adequate space, ventilation and lighting for every personnel to perform work safely;

(*g*) ensuring that all safety or emergency equipment are kept in good working order and there is an adequate stock of materials required for the handling of any medical emergency or adverse incident; and

(*h*) ensuring the cleanliness of every approved permanent premises.

(3) A licensee must keep up-to-date documentation of the policies and processes of the safety programme mentioned in paragraph (1) and make the documentation available to every personnel.

Licensee must ensure personnel comply with safety programme

14. A licensee must ensure that every personnel complies with the measures set out in the safety programme mentioned in regulation 13.

Personal protective equipment must be provided

15. A licensee must provide each personnel performing any work with personal protective equipment appropriate for the work performed.

PART 5

COLLECTION, STORAGE, DISTRIBUTION AND RETURN OF HUMAN TISSUE

Written consent required for collection and use

16.—(1) A licensee must, before collecting any human tissue or arranging for the collection of any human tissue by another person on behalf of the licensee, obtain prior written consent for the collection from —

(*a*) where the human tissue is to be collected from the body of a living donor — the living donor; or

(*b*) subject to paragraph (2), where the human tissue is to be collected from the body of a deceased individual — the authorised person.

(2) Paragraph (1)(*b*) does not apply where the human tissue is to be collected pursuant to —

(*a*) section 4(1) of the Human Organ Transplant Act 1987;

(*b*) a gift made by a deceased individual under section 3 of the Medical (Therapy, Education and Research) Act 1972; or

(*c*) a donation under section 4 of the Medical (Therapy, Education and Research) Act 1972.

(3) A licensee must, before obtaining the consent mentioned in paragraph (1) —

(*a*) provide the following information to the living donor or the authorised person, as the case may be:

(i) the purposes for which the human tissue collected is to be used;

(ii) every test that will be conducted on the human tissue for assessing the suitability of the human tissue for use;

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

(iv) the disposal of unused donated human tissue at the end of their viability period;

(v) where the human tissue is distributed for the purpose of transplant — that the licensee will disclose to the transplanting licensee to which the human tissue is distributed the following information:

(A) the medical history of the individual from whom the human tissue is collected;

(B) information relating to the licensee's testing and processing of the human tissue;

(vi) whether there is evidence of therapeutic use of the human tissue;

(vii) the options for how excess human tissue collected and other surgical residues are to be dealt with; and

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

(i) the licensee informing the donor of the abnormal finding or incidental finding;

(ii) the licensee informing the medical practitioner overseeing or performing the collection of the human tissue, or any medical practitioner

nominated by the donor, of the abnormal finding or incidental finding.

(4) A licensee must ensure that —

(*a*) the information mentioned in paragraph (3)(*a*) is explained to the donor or authorised person by a transplanting clinician or a transplant coordinator;

(*b*) the donor or authorised person is given sufficient time, after the information mentioned in paragraph (3)(*a*) is explained to the donor or authorised person, to decide whether or not to give consent under paragraph (1);

(*c*) the consent under paragraph (1) is not obtained by means of harassment, coercion, intimidation, deception, misrepresentation, reward or remuneration by any officer, employee or agent of the licensee; and

(*d*) records are kept in relation to the explanation of the information mentioned in paragraph (3)(*a*) that has been explained to the donor or authorised person.

(5) A licensee must not collect any human tissue if the licensee knows or has any reason to suspect that the consent given for the collection of the human tissue under paragraph (1) was obtained by reason of any harassment, coercion, intimidation, deception, misrepresentation, reward or remuneration by any person.

(6) Where a licensee handles, processes, tests, stores or distributes any human tissue from a living donor that is not collected by the licensee, the licensee must —

(*a*) obtain from the person who collected the human tissue a copy of the consent given by the living donor for the collection; and

(*b*) keep records of that consent.

(7) A licensee mentioned in paragraph (6) must not handle, process, test, store or distribute any human tissue from a living donor if the licensee knows or has any reason to suspect that the consent given by the living donor for the collection was obtained by reason of any

harassment, coercion, intimidation, deception, misrepresentation, reward or remuneration by any person.

(8) In paragraph (4), "transplant coordinator", in relation to a licensee, means a person who is the licensee's personnel and —

(*a*) has at least a diploma in nursing, science, social work or psychology;

(*b*) has at least 6 months on-the-job training under the supervision of a Clinical Governance Officer, transplanting clinician or another of the licensee's personnel with at least 2 years of experience providing donor counselling in relation to the provision of a human tissue banking service; and

(*c*) has been assessed by a Clinical Governance Officer or any suitably qualified personnel designated by a Clinical Governance Officer to have the appropriate competency in providing donor counselling in relation to the provision of the human tissue banking service.

Evaluation and screening of donors

17.—(1) A licensee must implement a system for evaluating the medical fitness and suitability of every donor.

(2) Without limiting paragraph (1), the licensee must ensure that the system mentioned in that paragraph includes all of the following matters:

(*a*) the collection of information —

(i) relating to the medical history of the donor known or available to the licensee;

(ii) relating to the medical history of the donor known or available to the donor or authorised person, as the case may be; and

(iii) where the medical history of the donor's immediate family is relevant in determining the suitability of the human tissue collected — relating to the medical

history of every member of the donor's immediate family;

(*b*) subject to paragraph (4), the signing of a declaration by the donor or authorised person (as the case may be), that all relevant information mentioned in sub-paragraph (*a*)(ii) and (iii) has been disclosed to the licensee, to the best of the knowledge of the donor or authorised person (as the case may be), at the time of making the declaration;

(*c*) a review by a medical practitioner of the information mentioned in sub-paragraph (*a*);

(*d*) where the donor is a living donor — a clinical evaluation of the donor conducted by a medical practitioner;

(*e*) a requirement for the donor of a type of human tissue, in relation to every infectious disease applicable to that type of human tissue as specified in the first column of the Second Schedule, to undergo all of the tests specified opposite that infectious disease in the second column of that Schedule;

(*f*) the conduct of all other necessary tests on the donor to assess whether the donor is eligible to donate the type of human tissue intended for donation.

(3) Every test mentioned in paragraph (2)(*e*) must be conducted using an appropriate test kit that has been validated for the purpose of donor testing.

(4) Paragraph (2)(*b*) does not apply where the human tissue is collected pursuant to —

(*a*) section 4(1) of the Human Organ Transplant Act 1987;

(*b*) a gift made by a deceased individual under section 3 of the Medical (Therapy, Education and Research) Act 1972; or

(*c*) a donation under section 4 of the Medical (Therapy, Education and Research) Act 1972.

(5) In this regulation —

"donor" includes a potential donor;

"immediate family", in relation to an individual, means the individual's biological parent or sibling.

Collection of human tissue

18.—(1) A licensee must, in relation to the collection of human tissue —

(*a*) develop and implement appropriate protocols for the safe and proper collection of human tissue to ensure the retention of the biological functions compatible with the intended use of the human tissue;

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

(*c*) provide all equipment and materials necessary for the safe and proper collection of the human tissue to ensure the retention of biological functions compatible with the intended use of the human tissue; and

(*d*) ensure that the donor is not subject to any procedure or test that is unnecessary for the purpose of collecting the human tissue.

(2) Where the human tissue is collected from a deceased donor, the licensee must keep and maintain records of —

(*a*) the time of cooling or refrigeration of the body of the deceased donor; and

(*b*) the time of cardiac death.

Processing, testing and quarantine of human tissue

19.—(1) To ensure the safety and quality, and, where applicable, the viability and potency, of the human tissue for transplant or other clinical use, a licensee must —

(*a*) implement appropriate and adequate processes for the processing, testing and quarantine of all human tissue in the possession or custody of the licensee; and

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

(2) Without limiting paragraph (1), a licensee must, in relation to the processing, testing and quarantine of human tissue —

(*a*) develop and implement written policies and procedures for the processing, testing and quarantine of human tissue;

(*b*) develop and implement written criteria and procedures for the evaluation and assessment of the quality of the human tissue for the purposes of storage or distribution, in particular the safety and quality, and, where applicable, the viability and potency, of the human tissue;

(*c*) where the human tissue is collected from the body of a deceased donor, ensure that the body is reconstituted with dignity and sensitivity;

(*d*) ensure that the environment within which the human tissue is collected, processed, tested and quarantined is appropriate to ensure the safety and quality, and, where applicable, the viability and potency, of the human tissue, and the safety of all personnel handling the human tissue;

(*e*) establish and validate the time period within which the processing and testing of human tissue has to be completed such that the human tissue remains suitable for its intended use at the end of that time period;

(*f*) ensure that the human tissue is collected, processed and stored within the appropriate time period for the particular type of human tissue to ensure the retention of the biological functions compatible with the intended use of the human tissue;

(*g*) ensure that the human tissue collected from a donor is not pooled with the human tissue collected from any other donor;

(*h*) take all reasonable steps to minimise the risk of contamination of the human tissue throughout the

processes of retrieval, processing and storage of the human tissue;

(*i*) use methods validated by the licensee and appropriate protocols for the processing and testing of human tissue, to maintain the safety and quality, and where applicable the viability and potency, of the human tissue and ensure the retention of the biological functions compatible with the intended use of the human tissue;

(*j*) where the size or dimensions of the human tissue processed by the licensee may be measured — keep and maintain records of the size or dimensions of the human tissue;

(*k*) maintain the traceability of all materials and equipment by keeping records of each material or equipment used to process any human tissue such that the specific material or equipment used to process the human tissue is known;

(*l*) before any human tissue (other than ocular tissue) is cryopreserved, ensure that representative microbiological cultures of the human tissue are obtained and tested for bacteria and fungi;

(*m*) discard the human tissue if any pathogenic and highly virulent microorganism is found to be present, unless treated with an appropriate sterilising procedure that has been validated to eliminate the infectivity of the microorganism;

(*n*) where the safety or quality, and, where applicable, the viability or potency, of the human tissue may be affected by its release into the licensee's inventory — quarantine the human tissue while it is being processed or tested; and

(*o*) ensure that any quarantined human tissue is released into the licensee's inventory or distributed to any other person only in accordance with the licensee's written criteria and procedures and with the approval of a Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer.

Storage of human tissue

20.—(1) A licensee must establish and implement an inventory management system to ensure that —

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

(*b*) the risk of contamination of the human tissue is minimised.

(2) Without limiting paragraph (1), the licensee must, in relation to the inventory management of any human tissue in the licensee's custody —

(*a*) store the human tissue in a validated container;

(*b*) package all human tissue appropriately;

(*c*) maintain the licensee's inventory system for the human tissue in the licensee's custody, including all human tissue under quarantine;

(*d*) internally audit the inventory system at appropriate intervals to ensure that the inventory system is accurate;

(*e*) implement an appropriate labelling system to ensure that each human tissue is correctly identified and traceable from the time of its collection to the time it is distributed;

(*f*) store all human tissue that has been tested and processed at an appropriate temperature;

(*g*) ensure that the storage requirements (including storage conditions and expiry date) for the human tissue is appropriate, having regard to —

(i) the type of human tissue concerned;

(ii) the requirements in regulation 19 for that type of human tissue; and

(iii) the intended use of that human tissue;

(*h*) ensure that the maximum storage period for every human tissue is appropriate, having regard to the following factors:

(i) the type of human tissue concerned;

(ii) the appropriate storage temperature for that type of human tissue;

(iii) the requirements in regulation 19 for that type of human tissue;

(iv) the intended use for that human tissue;

(*i*) ensure that any human tissue that is under quarantine is clearly labelled and segregated from any human tissue intended for distribution;

(*j*) where any human tissue is determined to be unsuitable for transplant or other clinical use, label the human tissue with all of the following:

(i) that the human tissue is unsuitable for transplant or other clinical use;

(ii) any other purpose for which the human tissue may be distributed; and

(*k*) distribute the human tissue only in accordance with the written consent by the donor or authorised person (as the case may be) and the requirements of any other written law.

Suitability of human tissue for distribution

21.—(1) A licensee must, before distributing any human tissue for transplant or other clinical use, evaluate whether the human tissue 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 human tissue.

(2) For the purposes of paragraph (1), a licensee must —

(*a*) before distributing any human tissue (other than ocular tissue) for transplant or other clinical use, test the human tissue for bacteria or fungi; and

(*b*) record the results of the tests conducted under sub-paragraph (*a*) in relation to the donor of the human tissue.

(3) If a licensee evaluates that any human tissue is not suitable for transplant or other clinical use under paragraph (1)(*a*) or (*b*) (as the case may be), the licensee must not distribute that human tissue for such transplant or clinical use.

Restrictions on distribution of human tissue

22.—(1) A licensee must not distribute any human tissue except with the approval of a Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer.

(2) A licensee must not distribute any human tissue to a person unless —

(*a*) the person is another licensee that is approved to provide a human tissue banking service for that type of human tissue;

(*b*) the person is licensed under the Act to provide a licensable healthcare service for the purpose of treating a condition treatable by the transplant of that type of human tissue; or

(*c*) where the person is established or incorporated outside Singapore — the person is licensed, registered, approved or otherwise regulated to carry on the activities of a human tissue bank or healthcare institution under the laws of the jurisdiction in which the person is established or incorporated.

(3) A licensee must not distribute any human tissue for a purpose in respect of which the donor or authorised person (as the case may be) has not given written consent.

(4) Where any human tissue is determined to be unsuitable for transplant or other clinical use, a licensee must ensure that the human tissue is distributed in accordance with the requirements of these Regulations and for a purpose for which the donor or authorised person (as the case may be) has given written consent.

Distribution of human tissue must be carried out in safe manner

23.—(1) A licensee must ensure that the distribution of human tissue for its intended purpose is carried out such that —

(*a*) the biological and functional properties of the human tissue are preserved; and

(*b*) the risk of contamination of the human tissue is minimised.

(2) Without limiting paragraph (1), a licensee must, in relation to the distribution of any human tissue —

(*a*) ensure that the human tissue is packaged and transported in a validated container;

(*b*) distribute the human tissue in the appropriate environmental conditions;

(*c*) take appropriate measures to ensure the human tissue is distributed to the intended recipient;

(*d*) establish and implement written policies and procedures for —

(i) the recall of the human tissue; and

(ii) the notification of any person who receives or has received the human tissue,

where the suitability of any human tissue for its intended use is or is believed to have been adversely affected for any reason; and

(*e*) ensure that an instruction sheet which includes all of the following information accompanies each human tissue distributed by the licensee:

(i) the specific storage conditions for the human tissue prior to its transplant or other clinical use;

(ii) any special requirement or measure that the medical practitioner using the human tissue must take to ensure the safe and effective use of the human tissue;

(iii) the measures that must be taken if there is any evidence of damage to or mislabelling of the human tissue or its packaging.

(3) A licensee must ensure that appropriate infection control measures are taken in the distribution of any human tissue collected from a donor who was, at the time of the collection, suffering from any infectious disease specified in the first column of the Second Schedule or any other infectious disease specified by a Clinical Governance Officer.

Approval of distribution by Clinical Governance Officer

24.—(1) A Clinical Governance Officer or designated personnel mentioned in regulation 22(1) must not approve the distribution of any human tissue for transplant or other clinical use under regulation 22(1) unless —

(*a*) the Clinical Governance Officer or designated personnel has reviewed —

(i) the results of any representative microbiological culture performed on the human tissue, 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 donor, including any variance from the applicable standard for determining the suitability of the human tissue for recipients determined by a Clinical Governance Officer; and

(*b*) the Clinical Governance Officer or designated personnel is satisfied that —

(i) the human tissue is safe and has met the licensee's written criteria and procedures for distribution; and

(ii) where the human tissue is non-conforming human tissue —

(A) there is clinical indication for the human tissue to be used for the transplant or other clinical use; and

(B) having regard to the particular circumstances, there is medical urgency to use the human tissue.

(2) In this regulation, "non-conforming human tissue" means human tissue that is —

(*a*) collected from a donor of any type of human tissue who was, at the time of the collection, suffering from any infectious disease applicable to that type of human tissue as specified in the first column of the Second Schedule or any other infectious disease specified by a Clinical Governance Officer; or

(*b*) determined by a Clinical Governance Officer to not have met all criteria of safety and quality, and, where applicable, the viability and potency, for transplant or other clinical use.

Provision of information relating to human tissue distributed for transplant

25.—(1) This regulation applies to a licensee in relation to any human tissue distributed by the licensee to a transplanting licensee for the purpose of transplant.

(2) The licensee must, in relation to the human tissue distributed, provide the results of tests conducted on the human tissue and the results of all screenings of the donor to the transplanting licensee and the transplanting clinician.

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

(*a*) the medical history of the donor;

(*b*) information relating to the licensee's testing and processing of the human tissue.

(4) The licensee must obtain from the transplanting clinician the following information, within the time that a Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer considers appropriate after the transplant has taken place:

(*a*) information concerning any adverse reaction arising from the transplant of the human tissue;

(*b*) information about the recipient of the human tissue.

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

Return of human tissue

26.—(1) A licensee must ensure that the return of unused human tissue from the person to whom it was distributed to the custody of the licensee is carried out —

(*a*) in a manner that preserves the biological and functional properties of the human tissue;

(*b*) in a manner that minimises the risk of contamination of the human tissue; and

(*c*) only where the criteria for the return of unused human tissue established by a Clinical Governance Officer are met.

(2) Without limiting paragraph (1), a licensee must —

(*a*) establish and implement policies and procedures for the return of unused human tissue;

(*b*) document the policies and procedures mentioned in sub-paragraph (*a*) and the criteria mentioned in paragraph (1)(*c*);

(*c*) take appropriate measures to examine the integrity of the validated container and the human tissue for contamination and mishandling; and

(*d*) take appropriate measures to ensure that any human tissue which may have been contaminated or mishandled is not placed back in the licensee's inventory.

Preventing spread of communicable disease

27. A 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 human tissue in the licensee's custody at any time, including the traceability of all equipment and materials used in the processing, storage, distribution or return of the human tissue.

Withdrawal of consent

28. Where a donor or an authorised person in relation to any human tissue collected by a licensee, at any time after the human tissue is collected but before the human tissue is distributed, informs the licensee that the donor or authorised person withdraws the consent for the use of the human tissue for any purpose, the licensee —

(*a*) must not distribute the human tissue for the purpose for which the consent was withdrawn; and

(*b*) must destroy the human tissue as soon as practicable after the donor or authorised person withdraws consent for every use of the human tissue.

PART 6

MISCELLANEOUS

Import of processed human tissue

29. A licensee must not, in relation to the provision of a human tissue banking service, import any processed human tissue from a person outside Singapore unless —

(*a*) that person is accredited by an accreditation body approved by the Director-General; or

(*b*) a Clinical Governance Officer approves the importation of the processed human tissue and the processed human tissue —

(i) is urgently needed for transplant to a victim of an event in which there are 10 or more persons injured in that event; and

(ii) is not available for importation from a person mentioned in paragraph (*a*).

Notification of abnormal or incidental findings

30.—(1) Where any human tissue was collected by a licensee from a living donor and —

(*a*) the living donor has, under regulation 16(3)(*b*), consented to be informed or for the licensee to inform a relevant medical practitioner of any abnormal or incidental finding pertaining to the living donor; and

(*b*) the licensee becomes aware of an abnormal or incidental finding relating to the living donor,

the licensee must inform the living donor or relevant medical practitioner (as the case may be) of the finding.

(2) Where —

(*a*) any human tissue from a living donor is handled, processed, tested, stored or distributed by a licensee but not collected by the licensee; and

(*b*) the licensee becomes aware of an abnormal or incidental finding pertaining to the living donor,

the licensee must inform the person from whom the licensee received the human tissue of the finding.

(3) In this regulation, "relevant medical practitioner" means the medical practitioner mentioned in regulation 16(3)(*b*).

Keeping of records — enabling identification of donor

31.—(1) A licensee must keep records of —

(*a*) the identity of the donor of each human tissue the licensee collects or receives;

(*b*) the identity of the recipient of each human tissue that the licensee has distributed human tissue to; and

(*c*) every human tissue bank that the human tissue was stored in from the time the human tissue was collected to the time the human tissue was transplanted or used for any other clinical use.

(2) A licensee must ensure that the records mentioned in paragraph (1)(*a*) and (*b*) are kept in a manner that enables the licensee to identify the donor for each human tissue received by a recipient.

(3) The licensee must keep every record mentioned in paragraph (1) (called an applicable record) confidential and ensure that —

(*a*) the confidentiality, integrity and security of every applicable record are maintained at all times; and

(*b*) every personnel handling any applicable record is aware of his or her role and responsibility in maintaining the confidentiality, integrity and security of the applicable records.

(4) In addition, where any information in an applicable record is in the form of an extract or aggregated compilation, the licensee must ensure that the confidentiality, integrity and security of the information in the extract or aggregated compilation are maintained at all times.

(5) The licensee must —

(*a*) implement adequate safeguards and appropriate protocols and processes to protect the applicable records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification; and

(*b*) periodically monitor and evaluate the safeguards, protocols and processes mentioned in sub-paragraph (*a*) to ensure that they are effective and being complied with by the personnel involved in handling the applicable records.

Keeping of records — general requirements

32.—(1) A licensee must —

(*a*) maintain proper, complete and accurate records of every programme, policy, system, measure, protocol or process that the licensee is required to implement under these Regulations, and every activity undertaken under or change made to that programme, policy, system, measure, protocol or process;

(*b*) maintain proper, complete and accurate records of each human tissue that is received by the licensee for processing, including the time at which the human tissue is received for processing;

(*c*) maintain records of every approval given by a Clinical Governance Officer or any other suitably qualified personnel designated by a Clinical Governance Officer under these Regulations;

(*d*) maintain records of every policy and procedure established by a Clinical Governance Officer under these Regulations; and

(*e*) take reasonable steps to ensure the confidentiality, integrity and security of every record mentioned in sub-paragraphs (*b*) and (*c*).

(2) Without limiting paragraph (1), the licensee must —

(*a*) establish and implement a process to ensure there is proper document control of all documents relating to the human tissue banking service;

(*b*) ensure that a Clinical Governance Officer approves, signs and dates each record mentioned in paragraph (1)(*a*); and

(*c*) ensure that at least one personnel is responsible for the document control of all documents relating to the human tissue banking service.

(3) The licensee must ensure that each record mentioned in paragraph (1)(*a*) is available for reference at all times by each personnel.

Continuity of operations

33.—(1) A licensee must establish a contingency plan to ensure that the safety and quality, and, where applicable, the viability and potency, of all human tissue 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 human tissue in the licensee's custody to another licensee;

(*b*) processes to inform, without undue delay, a relevant donor of the proposed transfer or disposal of any human tissue as a result of the disruption to the licensee's operations;

(*c*) processes to obtain the express written consent of the relevant donor for the proposed transfer or disposal in the event of any disruption to the licensee's operations;

(*d*) where there is any human tissue in the licensee's custody that was not collected by the licensee — processes to inform, without delay, the person from whom the licensee received the human tissue, of the proposed transfer or disposal of any human tissue as a result of the disruption to the licensee's operations.

(3) In this regulation, "relevant donor" means a donor who donated human tissue only for autologous use or use by a specified individual.

Transfer of human tissue to another human tissue bank

34. Where any human tissue is to be transferred to another person (called in this regulation the transferee), the licensee must ensure that —

(*a*) the transferee is another licensee or a person in a foreign jurisdiction that is licensed, registered, approved or otherwise allowed to carry on the activities of a human tissue bank under the laws of the foreign jurisdiction; and

(*b*) there is a written agreement setting out the terms of the transfer of the human tissue.

Tests on persons must be conducted by licensed persons or accredited laboratories

35. Where a licensee requires a person to undergo any test in the course of the licensee's provision of the human tissue banking service, the licensee must —

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

(i) a person that holds a licence under the Act authorising the person to provide a clinical laboratory service; or

(ii) a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General; and

(*b*) retain a copy of any clinical laboratory report issued by the person mentioned in paragraph (*a*)(i) or (ii) for the test.

Outsourcing

36.—(1) Subject to this regulation, a licensee must not appoint any person to provide, on the licensee's behalf, a human tissue banking service or any aspect of the human tissue banking service.

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

(*a*) another licensee that is approved to provide a human tissue banking service for the same type of human tissue;

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

(*c*) a person who operates a human tissue bank for the same type of human tissue or a clinical laboratory outside Singapore that is accredited by an accreditation body acceptable to the Director-General.

(3) Where a licensee has appointed a person under paragraph (2) to conduct any test of any human tissue, 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 33, appoint any person to process, store or distribute any human tissue on the licensee's behalf.

(5) To avoid doubt, a licensee that appoints another person to carry out 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

37. A licensee must, before providing the human tissue banking service to the donor, authorised person or recipient (called in this regulation the client) —

(*a*) inform the client of all applicable charges (including administrative charges) relating to the provision of the human tissue banking service, where applicable; and

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

Offences

38.—(1) A person who contravenes regulation 10(1), 11(1), 12(1), 13(1), 14, 16(4), (5) or (7), 17(1), 18(1), 19(1), 20(1), 21(1), (2) or (3), 22(1), (2), (3) or (4), 23(1) or (3), 24(1), 25(2), (3) or (4), 26(1), 27,

28, 29, 30(1) or (2), 31(1), (2), (3), (4) or (5), 32(1), 33(1), 34, 35 or 36(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 —

(*a*) to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(*b*) 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.

FIRST SCHEDULE

Regulations 4 and 5

SPECIFIED SERVICES

The handling, processing, testing, storage and distribution of any of the following types of human tissue:

1. adipose tissue
2. amniotic membrane
3. birth tissue (excluding amniotic membrane)
4. bone (excluding bone marrow)
5. cardiac tissue
6. connective tissue membrane
7. dura mater
8. epithelial membrane (except skin)
9. haematopoietic stem cell (including bone marrow)
10. lymph tissue
11. nervous tissue
12. ocular tissue
13. parathyroid tissue
14. skeletal muscle tissue
15. skin tissue

FIRST SCHEDULE — *continued*

16. smooth muscle tissue
17. tendon, ligament or cartilage tissue
18. vascular tissue

SECOND SCHEDULE

Regulations 17(2)(*e*), 23(3) and 24(2)(*a*)

INFECTIOUS DISEASES

First column	*Second column*
A. For any type of human tissue including haematopoietic stem cells	
1. Hepatitis B infection	(*a*) serology (*b*) nucleic acid test
2. Hepatitis C infection	(*a*) serology (*b*) nucleic acid test
3. Human immunodeficiency virus (HIV) infection	(*a*) serology (*b*) nucleic acid test
4. Syphilis	(*a*) serology
B. For haematopoietic stem cells only	
5. Cytomegalovirus	(*a*) serology

Made on 20 June 2023.

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

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