

# GUIDELINES FOR HEALTHCARE INSTITUTIONS PROVIDING TISSUE BANKING: REGULATION 4 OF THE PRIVATE HOSPITALS AND MEDICAL CLINICS REGULATIONS (CAP 248, RG 1)

## 1 DEFINITIONS

- 1.1 Unless used in another context in these guidelines or otherwise defined in any tissue-specific manuals, the following terms shall be defined as follows:
- a. *Human tissue* includes all constituent parts of the human body, including surgical residues, but excluding solid organs, hairs, nails, body waste products, placenta, blood and blood products as well as reproductive tissue, such as sperms, eggs and embryos.
  - b. Tissues which have been processed in such a manner that their functional, structural and biological characteristics have been altered are considered as biologics and are not classified as tissues. Such biologics are not governed under these guidelines. Examples of biologics include myoblasts and tissues used as part of gene therapy technology.
  - c. *Tissue Banking* refers to the activities of donor screening, procurement, processing, storage and distribution of human tissue intended for transplantation into a human.
  - d. A *Tissue Bank* is deemed to exist when it conducts any of the activities of Tissue Banking stipulated in 1.1c. for tissues defined under 1.1a. A facility that processes and handles biologics as defined under 1.1b is not considered to be a Tissue Bank and is not governed by the requirements of these guidelines.
  - e. A *donor* is the source of the tissues governed by these guidelines and unless otherwise stated, refers to both a living donor and cadaveric donor.
  - f. A *transplant practitioner* is the person who performs transplantation procedures.
  - g. A *recipient* is the individual into whom a tissue is transplanted.

## 2 ESTABLISHMENT OF TISSUE BANKS

- 2.1 Tissue banks may only be established in healthcare institutions licensed under the Private Hospitals and Medical Clinics Act ("the Act").

- 2.2 The application form to set up a Tissue Bank must be submitted to the Director of Medical Services not less than 30 days before the intended date to commence the operations of the Tissue Bank. Forms may be obtained from the Licensing and Accreditation Branch, Ministry of Health.
- 2.3 The operation of any Tissue Bank may only be undertaken after the healthcare institution obtains the relevant approval of the Director of Medical Services ("DMS") to establish and operate such a facility. Applications for such approval must be in accordance with the Private Hospitals and Medical Clinics Regulations ("the Regulations").
- 2.4 The operation of the Tissue Bank must comply strictly with the conditions, if any, prescribed by the DMS as well as with these guidelines.
- 2.5 If approval given to a healthcare institution to establish and operate a Tissue Bank is revoked by the DMS, the institution must cease operation of the facilities within the time specified by the DMS.

### **3 STAFFING AND ORGANISATION**

#### Director

- 3.1 The healthcare institution, which has obtained the approval, shall appoint a Director of the Tissue Bank (hereafter referred to as "the Director") who shall manage and be responsible for all the activities performed by the Tissue Bank.
- 3.2 The Director shall be a doctor currently registered with the Singapore Medical Council and shall be qualified by training and experience for the scope of activities being performed by the Tissue Bank.
- 3.3 The Director may delegate the administrative, technical, regulatory, compliance, safety issues and other general activities to an Administrator, but all medical activities shall remain the sole responsibility of the Director. Medical activities include, but are not limited to:
  - a. Documentation of donor suitability prior to release of tissue into the inventory for distribution
  - b. Approval of the release of each batch of tissue following processing
  - c. Approval and regular review of all standard operating procedures of a medical and technical nature
  - d. Review and evaluation of reports and investigation of errors, accidents, adverse reactions/outcomes and complaints of a medical/technical nature

- 3.4 The Director must ensure that the Administrator shall have the experience and a clear understanding of the scientific principles and techniques involved in the tissue banking activities.

#### Technical Staff

- 3.5 There shall be an adequate number of qualified and trained technical personnel to supervise and perform all activities of the Tissue Bank.
- 3.6 The technical personnel shall have an educational background, documented training and experience commensurate with their assigned duties and a thorough understanding of the procedures and activities they perform.

## **4 FACILITIES**

- 4.1 The facilities of the Tissue Bank shall be of suitable size, location and design to accommodate all personnel, fittings and equipment and to allow all activities, procedures and movements to be carried out in comfort and safety.
- 4.2 The facilities shall be maintained in a clean, tidy and sanitary condition.
- 4.3 All instruments and equipment must be subjected to regular maintenance and calibration. These shall include regular maintenance to be performed on each piece of instrument/equipment, documentation of maintenance completed and corrective actions taken, if any. Maintenance manuals for all instruments and equipment must be kept updated and available at all times.
- 4.4 Equipment and non-disposable items that come into contact with tissues shall be sterilised or decontaminated after each use according to prevailing guidelines in Singapore (e.g. the “Guidelines for Preventing Transmission of Bloodborne Infection in A Healthcare Setting” issued by the Ministry of Health).
- 4.5 Biohazards and other hazardous waste items must be disposed of in a manner that would minimize the hazards to the Tissue Bank including personnel and the environment, and conform to existing legislation and relevant guidelines issued by the Ministry of Health and the National Environment Agency.
- 4.6 Environment monitoring procedures shall be established, when appropriate, for tissue processing facilities.
- 4.7 Access to the Tissue Bank shall be limited to authorised persons who are appointed by the Director.

## **5 QUALITY ASSURANCE PROGRAMME**

### **5.1 General**

- a. The Director shall be responsible for the overall Quality Assurance Programme of the Tissue Bank
- b. Standard Operating Procedures, including tissue processing, preservation, packaging and storage shall be validated to demonstrate the consistent effectiveness of the procedures.
- c. Tests and procedures shall be performed periodically to measure, assay or monitor processing, preservation and storage methods, equipment and reagents to ensure compliance with established tolerance limits. Results of all such tests or procedures shall become part of the permanent record.

### **5.2 Records**

- a. All donor information (which includes, but not limited to biographic and medical information), processing, storage and distribution records must be maintained indefinitely.
- b. There shall be an identification system to link the donor with each tissue allograft and to permit tracking of tissues from donation to distribution to the end-user or other final disposition.
- c. Records must be maintained so that tissue can be promptly tracked and located.
- d. All measures must be taken to keep the records securely and to maintain the confidentiality of information relating to donor and their tissues.

### **5.3 Errors, Accidents and Adverse Reactions/Outcomes**

- a. There shall be written procedures for receiving, evaluating, investigating and documenting errors and accidents related to donor screening, tissue procurement, processing, storage and distribution.
- b. There shall be written procedures for receiving, evaluating, investigating and documenting suspected adverse reactions/outcomes.
- c. There shall be written procedures for recall of tissues or notification of recipient centers of the possibility of tissue contamination, defects in processing, preparation of distribution, or other factors affecting suitability of the tissue for their intended application.

- d. All adverse reactions must be reviewed by the Director of the Tissue Bank.
- e. The Director shall notify the DMS within one working day of any significant error or accident (i.e. with the potential to cause death or serious morbidity) involving the Tissue Bank, transmission of disease via tissue graft or fatal or adverse reaction/outcome arising from the receipt of tissues from the Tissue Bank.

## **6 DONOR'S CONSENT**

- 6.1 Informed consent shall be obtained from all donors for the use of their tissue for specified purposes and for serological testing. The use of tissue from cadaveric donor should be in accordance with prevailing relevant legislation.
- 6.2 In the case of discarded tissue or surgical by-product, the patient shall be made aware that he or she can express any intention as to how he or she desires such surgical residues to be dealt with or else the surgical residues would be handled by the healthcare institution as it deems fit.

## **7 DONOR SCREENING AND DONOR TESTING**

- 7.1 Individual evaluation of each potential donor shall include a review of the clinical history and a thorough clinical evaluation.
- 7.2 There shall be clearly documented criteria for the selection and acceptance of tissues, which are in accordance with existing professional practice. Tissue shall be rejected if there is a clinical history of one of the following diseases :
  - a. Malignant diseases except primary basal cell carcinoma of the skin, primary brain tumors and any treated and healed carcinoma in situ. For corneal tissues, only lymphoproliferative disorders, leukemias, and malignant tumors of eyes shall be contraindications
  - b. Viral hepatitis, HIV infection, active tuberculosis or untreated syphilis
  - c. Septicemia and systemic viral disease or mycosis
  - d. Risk of Creutzfeldt-Jakob Disease transmission i.e. Donors who receive human growth hormone or who have a family history of dementia and/or neurodegenerative disease.
  - e. High risk category for HIV infections or Hepatitis

- 7.3 The minimum serological tests with consent when appropriate shall include:
- a. Human immunodeficiency virus antibody (HIV I and II)
  - b. Hepatitis B virus surface antigen (HBSAg)
  - c. Hepatitis C virus antibody (HCV)
  - d. Syphilis

## **8 PRACTICES**

- 8.1 The procedures and practices for all Tissue Banking activities must be set out in detail in procedure manuals. These procedure manuals must be kept updated and made available at all times to all personnel of the Tissue Bank.

### Tissue Retrieval

- 8.2 Tissues from donors shall be retrieved and preserved within the time interval appropriate for retention of biological functions compatible with the intended use of those tissues.
- 8.3 Every effort shall be made to minimise contamination of tissue during the retrieval.
- 8.4 Reconstitution of the body of cadaveric donors shall be conducted with dignity and sensitivity.

### Tissue Processing

- 8.5 Tissue must be processed according to the Tissue-Specific Manuals established for each tissue.
- 8.6 Tissue from more than one donor shall not be pooled during processing, preservation and storage.
- 8.7 Methods used for tissue preservation must be appropriate for the type of tissue and must ensure the retention of the properties of the tissue consistent with the intended use of the tissue.
- 8.8 Storage containers shall be appropriate for the type of tissue and its intended application.

### Labelling

- 8.9 All containers of tissue shall be clearly labelled. The label shall include:
- a. Tissue identification number and batch, if applicable

- b. Proper name of tissue product
  - c. Amount of tissue in the container expressed as volume, weight, dimension etc, as appropriate
  - d. Expiry date
  - e. Recommended storage temperature
  - f. Name of Tissue Bank
- 8.10 Tissues determined to be unsuitable for transplantation and intended for release for other purposes (e.g.research) shall be clearly labelled accordingly.

### Storage

- 8.11 The temporary storage container used for unprocessed tissues must be appropriate for the tissue.
- 8.12 The storage requirements for a tissue, including storage temperature, storage services and expiry date, shall be appropriate to the type of tissue, packaging, processing as well as to its intended application.
- 8.13 Storage equipment shall be regularly maintained, calibrated and monitored according to written procedures.

### Quarantine

- 8.14 Tissues shall be quarantined at any phase of the operation when their release could affect the safety, effectiveness or quality of those tissues.
- 8.15 Quarantine areas shall be physically separated from areas storing tissues available for distribution.

## **9 GENERAL**

- 9.1 Provision of tissues for transplantation shall be restricted to other Tissue Banks and transplant practitioners.
- 9.2 An instruction sheet must accompany all tissues distributed. It shall contain the following information, if relevant:
- a. The appropriate storage condition prior to transplant
  - b. Information regarding any special care required by the transplant practitioner for the safe and most effective use of the tissue (e.g. Preparation of tissue for transplantation)

c. Actions to be taken if there is evidence of breakage, mislabelling, etc.

9.3 Donor medical history, tissue related information and tissue processing details shall be made available to the transplant practitioner and other Tissue Banks upon request, except where such information may infringe on confidentiality of the donor.

#### Imported Tissues

9.4 The Tissue Bank which imports the tissue shall be responsible for the quality and safety of the tissues imported.

#### Reimbursements and Charges

9.5 No monetary compensation or payment, except for the reimbursement of donation related expenses, shall be made to living donors, next of kin, or the donor's estate or any authorised person who donates the tissue.

9.6 The sole basis of charges imposed by the Tissue Bank shall be for the recovery of the actual cost of tissue banking activities.

Dated this      day of March 2003

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