MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation on the Healthcare Services Human Tissue Banking Service Regulations

Presented by Health Regulation Group
Ministry of Health
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Agenda

Objectives

This presentation will highlight:

1. **Who** the Human Tissue Banking Service Regulations apply to under the Healthcare Services Act ("HCSA").

2. **What** the key changes are for the provision of Human Tissue Banking Service under the HCSA, from the existing requirements under the Private Hospitals and Medical Clinics Regulations ("PHMCR") and Guidelines for Healthcare Institutions Providing Tissue Banking ("Guidelines").

Human Tissue Banking Service Regulations

1. The Human Tissue Banking Service Regulations will be **published by end May 2023.**

2. Licensees must comply with the abovementioned Regulations from **mid June 2023** upon transition to HCSA licences.

3. Regulations **will be complemented with:**

   a) Licence Conditions ("LCs") that set out specific technical requirements to be met.

4. Requirements that are "new" or "enhanced" compared to the existing PHMCR requirements and Guidelines are highlighted as such.

Definition of Human Tissue Banking Service

1. Human Tissue Banking Service under the HCSA refer to the **handling, processing and storage of human tissue** which is derived or obtained from the body of an individual and **distributed for subsequent therapeutic use^** in the body of the same or another individual, and includes the screening of any donor, but excludes the following:

   a) any blood banking service, cord blood banking service or reproductive cell and embryo banking service within an assisted reproduction service, and the storage of human tissues for 48 hours or less where the human tissue is intended for immediate transplant upon retrieval from the human body.

2. "Human tissue" means all constituent parts of the human body except:

   a) Blood, blood components, and blood products;
   b) Cord blood;
   c) Any embryo;
   d) Hairs;
   e) Nails;
   f) Naturally excreted or secreted bodily fluids and waste products such as saliva, sweat, urine and faeces;
   g) Reproductive cells;
   h) Cell, tissue and gene therapy products which contain human cells or tissues that are more than minimally manipulated;
   i) Nucleic acids.

^Not applicable for human tissue used in research, which comes under the purview of the Human Biomedical Research Act (HBRA).

Requirements under Human Tissue Banking Service Regulations

A. Licensing Matters

i. Modes of Service Delivery and Specified Services [NEW]

B. Governance and personnel

i. Oversight of human tissue banking [ENHANCED]

ii. Duties and responsibilities of Clinical Governance Officer [NEW]

iii. Staff involved in provision of service [ENHANCED]

C. Facilities and equipment

D. Service provision

i. Donor recruitment, evaluation and collection

ii. Evaluation and screening of potential donors, etc. [ENHANCED]

iii. Collection of human tissue [NEW]

iv. Processing, testing and quarantine

v. Storage and distribution

vi. Re-identification and notification of donors in event of incidental findings [NEW]

vii. Provision of information relating to human tissue for clinical use

viii. Information relating to human tissue for transplant

ix. Outsourcing of tests

x. Price transparency

E. Quality Management Systems

i. Quality Management System [ENHANCED]

F. Documentation

G. Preserving continuity of care [NEW]

Licensing Matters

[NEW] Modes of Service Delivery and Specified Services

1. Human Tissue Banking ("HTB") Service may only be provided out of permanent premises (i.e. brick and mortar healthcare establishment).

2. Where the licensee stores tissues in different permanent premises, they must hold one licence for each permanent premises.

3. The specified services ("SSes") under HTB are listed below:

    a) Ocular tissue;
    b) Skin tissue;
    c) Cardiac tissue;
    d) Bone (excluding bone marrow);
    e) Haematopoietic stem cells (including bone marrow);
    f) Vascular tissue;
    g) Parathyroid tissue;
    h) Others.

Governance and Personnel

[ENHANCED] Oversight of Human Tissue Banking service

Human tissue banking licensee must appoint the following individuals to oversee the provision of the service:

Personnel	Requirement
Clinical Governance Officer	1. Registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner; 2. Registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of medicine relevant to the specified service; and 3. At least 5 years of work experience in — a) human tissue banking; or b) cord blood banking; or c) blood banking.

[NEW] Duties and responsibilities of Clinical Governance Officer (CGO)

To prescribe specific duties and responsibilities of the CGO that are essential to ensure proper clinical governance.

1. Set and implement appropriate policies, processes and programmes for the clinical and technical aspects of the service.
2. Provide **clinical and technical governance and oversight** of the service.
3. Assist licensee in the **day-to-day clinical and technical management** of the service to ensure compliance with relevant regulatory requirements.
4. **Implement and regularly review systems** for clinical governance, risk management and quality management:
    a) Detect and address any risks affecting patent safety, welfare or the continuity of care in a timely manner;
    b) Promptly address and remedy any weaknesses or inadequacies in the provision of the service.

[NEW] Duties and responsibilities of Clinical Governance Officer (CGO)

To prescribe specific duties and responsibilities of the CGO that are essential to ensure proper clinical governance.

5. Ensure **proper supervision, continuous competency assessment and training** of staff involved in the clinical and technical aspects of the service:
   a) Staff acquire and maintain the requisite skills and competencies to perform their work and the relevant knowledge to ensure their safety when performing their work;
   b) The focus of the CGO is to provide oversight on staff training (e.g. advise on the type and frequency of training needed), and develop the supervisory framework which encompasses delegation of work, escalation of issues, etc.
6. Evaluate any test method that it performs in accordance with the manufacturer's specifications (if any) and produces accurate results before implementation.

[ENHANCED] Staff involved in provision of service

To ensure staff providing the service are adequate, appropriate and qualified.

1. There is an **adequate number** of staff to provide the service in a safe manner.
2. Every staff member has the **necessary qualifications, training and competence**, with regard to the type and nature of work performed by that staff member.
3. Licensee must ensure that every staff member:
   a) Is adequately trained for the work performed by the staff member and attends regular training in accordance with a continuous training programme;
   b) Has the relevant awareness and knowledge of to ensure the safe provision of the service; and
   c) Is assessed periodically on his/her competencies and work performance, before independent performance of the assigned tasks.
4. Staff with less than 2 years of relevant work experience must perform any task in relation to human tissue banking **under the close supervision** of the CGO or another designated staff member with at least 5 years of relevant work experience.

Facilities and Equipment

Premises, Equipment and Supplies

Facilities, equipment, supplies etc.

To ensure that service is provided in a safe and suitable environment, using appropriate equipment.

The licensee must ensure that every licensed premises is safe, secure, appropriate and adequate for service provision:

Aspect	Requirements
Access to banking facilities	1. Access to the banking facilities is restricted to individuals authorised by the CGO.
Environment	2. Procedures in place to **monitor and maintain the conditions** in which all human tissues are stored, including the immediate notification of and response to temperature deviations outside acceptable ranges. **3. Safety procedures** developed and implemented that are compliant with requirements under any other written law relating to workplace safety and health.
Power supply for laboratory equipment	**4. Adequate, stable and appropriate electric supply** is provided for all laboratory equipment, including an adequate number of grounded electrical outlets and an **emergency power supply** for each equipment that is essential for maintaining the integrity of human tissue.

Premises, Equipment and Supplies

Facilities, equipment, supplies etc.

To ensure that service is provided in a safe and suitable environment, using appropriate equipment.

Aspect	Requirements
Equipment, supplies and reagents	5. Instruments and equipment are **validated and commissioned for use.** 6. Refrigerators / storage tanks undergo **periodic maintenance** to ensure quality and usability of human tissue and reagents, and have **clearly demarcated and labelled** areas for human tissue stored. 7. All equipment and supplies are **effective to ensure the safety, quality of human tissue.** 8. Procedures are in place to monitor, inspect, sterilise and clean each piece of used equipment. **9. Appropriate tests and procedures are carried out periodically** to ensure equipment or reagent used complies with at least the tolerance limits determined by the manufacturer. 10. Information on the name of manufacturer, the name, lot number and expiration date of supplies and reagents are identified and recorded. 11. Sterilised instruments, supplies and reagents are **clearly labelled** to indicate the date that they have been sterilized. 12. Suppliers of any material, which use has or is likely to have a material impact on the safety and quality of human tissue, are selected and **evaluated regularly.**

Provision of Healthcare Service

Donor recruitment, evaluation and data collection

[ENHANCED] To ensure adequate and appropriate pre-donation counselling and obtain informed consent for the human tissue.

1. Human tissue banking licensee must ensure that the following is obtained:

   a) For donors who have pledged the donation of tissues for retrieval under the Human Organ Transplant Act (HOTA) or the Medical (Therapy, Education and Research) Act (MTERA):
      i. To follow consent and counselling requirements prescribed under HOTA and MTERA.

   b) For all other donors*:
      i. Counselling to be done by a transplant physician relevant to the tissue intended for treatment;
      ii. The counselling must include the intended use and evidence of therapeutic use (details in the next slide);
      iii. Express written consent must be obtained from the donor.

2. **Adequate records** of the counselling provided are to be maintained.

**In the case of minor donors, the licensee shall obtain consent from and provide counselling to the minor's parent or legal guardian.*

Donor recruitment, evaluation and data collection

[ENHANCED] To ensure adequate and appropriate pre-donation counselling and obtain informed consent for the human tissue.

For non-HOTA/MTERA donors*:

1. At the point of consent, the licensee must counsel the donor on:
    a. The purposes for which the human tissue is to be used (i.e. including evidence of therapeutic use);
    b. Any tests necessary to assess the suitability of the human tissue for use;
    c. The disposition of unused donated tissues (i.e. including tissue found to be of low potency/contaminated);
    d. Disclosure of the donor's medical information to the transplanting clinician upon transplant;
    e. Re-identification consent of the donor in the event of any abnormal or incidental finding;
    f. Consent to notify the medical practitioner (caring for the donor) in the event of any abnormal or incidental finding; and
    g. That the donor shall have the right to withdraw his or her consent at any time.

2. Licensee must not obtain donor's consent by means of coercion, intimidation, deception, harassment or misrepresentation by any employee or agent.

3. Licensee must not obtain donor's consent by means of reward or renumeration by any employee or agent.

**In the case of minor donors, the licensee shall obtain consent from and provide counselling to the minor's parent or legal guardian.*

Donor recruitment, evaluation and data collection

To collect and secure information about donors of human tissue.

The licensee must:

a) Put in place an identification system that ensures linkage between the recipient of each human tissue to its donor;
b) Ensure that the system allows for the tracking of human tissue from its acquisition to its final use (i.e. including from overseas sources);
c) Protect the confidentiality of all such information in its custody or under its control;
d) Keep and maintain accurate records; and
e) Keep the following donor's records with reference to the Licence Conditions on the Retention Periods of Patient Health Records:
    i. Donor's consent records;
    ii. Donor's health records.

Electronic Health Records	Paper Health Records
Lifetime + 6 years	**Adults:** 15 years
	Minors: Until the patient is 24 years of age; or 15 years from last day of: (i) stay in the facility, or (ii) consultation or treatment (if applicable), whichever is later.
	Persons who lack mental capacity: Lifetime + 6 years

[ENHANCED] Evaluation and screening of potential donors, etc.

1. A system must be implemented to **evaluate the fitness and suitability** of every individual who will be donating any human tissue, including a review of the potential donor's **medical history**, and a **clinical evaluation** of the potential donor by a medical practitioner.
   a) There should be a **signed declaration** made by a potential donor or authorized person in relation to the donor's personal medical history and the medical history of his/her immediate family members (i.e. blood-related parents and siblings)*.

2. As part of the evaluation and screening process of donors, the licensee must ensure:
   a) The donor has undergone screening in relation to the infectious diseases specified in the Schedule (Annex A) via validated test methods;
   b) Any other necessary tests for donor eligibility; and
   c) Communication of any abnormal results (including incidental findings) to the living donor, and the medical practitioner (if consented).

**Medical history of immediate family members are not required for ocular and skin tissue donors.*

[ENHANCED] Evaluation and screening of potential donors, etc.

3. **Every human tissue donor is screened** using appropriate and validated test methods for the following diseases* (Annex A):
   a) Hepatitis B virus;
   b) Hepatitis C virus;
   c) Human immunodeficiency virus (HIV) infection;
   d) Syphilis;
   e) Cytomegalovirus;
   f) Human T-cell lymphotropic virus types I and II.

4. The licensee must ensure that the donor screening test is conducted by:
   a) A clinical laboratory service or blood banking service licensee under HCSA;
   b) An accredited overseas clinical laboratory or blood bank approved by the Director.

5. Human tissue from a donor screened positive for any of the diseases stipulated above or determined not to have met all criteria for safety, quality may only be banked & distributed **at the approval of the CGO.**

**Screening test requirements depend on tissue type to be banked.*

[NEW] Collection of human tissue

1. Licensee must ensure that the donor's human tissue is collected in a manner that ensures **acceptable product end point** (i.e. tissue viability, level of contamination). This entails:

   a) Development and implementation of appropriate protocols for the safe and proper collection of human tissue;

   b) Proper training and competency of staff performing the human tissue collection and handling;

   c) Provision of adequate equipment and materials necessary for the safe and proper collection and transport/transfer of human tissue.

[NEW] Import of human tissue from overseas sources

1. Licensee must ensure the quality, safety of any **imported human tissue.**

   a) Licensee should only accept human tissue from overseas sources accredited by an **accreditation body approved by the Director;**

   b) The list of accredited bodies can be found in Annex B.

Processing, testing and quarantine

To ensure quality assurance of human tissue for clinical use.

The licensee shall **implement processes for the processing, testing and quarantine** of human tissue to **ensure their safety and quality** for transplant or clinical use, and identify and implement all tests that may be necessary.

Processing

1. Develop and implement procedures for the processing of the human tissue.
2. **Reconstitute the body with dignity and sensitivity**, where the human tissue is collected from a deceased donor.
3. **Establish an appropriate environment** to ensure the safety and quality of the human tissue, and the safety of the human tissue handlers.
4. Ensure that the collected human tissue is **processed within the appropriate time period** to retain its biological functions.
5. Ensure that the human tissue collected from a donor is **not mixed together** with that from any other donor.

Processing, testing and quarantine

To ensure quality assurance of human tissue for clinical use.

Processing

6. Take all reasonable steps to **minimise the risk of contamination** of the human tissue.
7. Use **validated methods and appropriate protocols** for the processing (including cryopreservation) of human tissue to maintain its quality and safety.
8. Establish and validate the time period within which the processing of human tissue has to be completed with an acceptable product end point.
9. **Maintain records of:**
   a) The size or dimensions of solid human tissues processed (where applicable);
   b) The time of cooling or refrigeration of the deceased donor's body (where applicable);
   c) The time of cardiac death of the deceased donor (where applicable).
10. **Maintain the traceability** of all materials and equipment used to process the human tissue.

Processing, testing and quarantine

To ensure quality assurance of human tissue for clinical use.

Testing

1. **Establish and implement procedures** for the evaluation and assessment of human tissue's quality and safety.

2. **Obtain representative microbiological cultures** for any human tissue^ that is to be stored, distributed for transplant or clinical use, and the cultures are to be **tested for bacteria or fungi**
   a) Results are to be documented in the donor record#.

3. **Discard or treat the human tissue** with a validated sterilisation procedure before use if any of the pathogens are found to be present:
   a) Fungi such as yeasts and moulds;
   b) Clostridium species;
   c) Streptococcus pyogenes.

^with the exception of Ocular tissue.
#Results to be reviewed by the CGO or the CGO's designee before the human tissue can be distributed for transplant or clinical use.

Storage and distribution

Proper return of human tissue to ensure safety and quality for clinical use.

All unused human tissues are **returned** to the licensee such that the **biological and functional properties of the human tissues are preserved**, and the **risk of contamination is minimised.**

1. Establish and implement written procedures to **permit the return** of unused human tissue.

2. Examine the **integrity of the validated container and human tissue** for contamination and mishandling before releasing the tissue back to inventory.

Processing, testing and quarantine

To ensure quality assurance of human tissue for clinical use.

Testing

4. The following must be **reviewed by the CGO** or his/her designee before any human tissue is distributed for transplant or clinical use:
   a) Results of any microbial culture performed on the human tissue, including any variance from relevant standard or benchmark;
   b) Any other test results on donor suitability, including any variance from relevant standard or benchmark;
   c) Any human tissue which was banked at the CGO's discretion.

Processing, testing and quarantine

To ensure quality assurance of human tissue for clinical use.

Quarantine

1. Any human tissue must be quarantined while it is being processed or tested where the safety and quality of the human tissue is likely to be affected by its release into the inventory.

2. Any human tissue that has been quarantined must only be released into the inventory or distributed to any other person with the approval of the CGO.

Processing, testing and quarantine

Suitability of recipient of human tissue.

1. The CGO must, in relation to the distribution of any human tissue in its custody for transplant or clinical use, **evaluate whether the human tissue is suitable:**
   a) For transplant or clinical use generally; and
   b) For transplant to or clinical use by the proposed recipient of the human tissue.

2. Where the licensee is aware of any adverse reaction in relation to the transplant or clinical use of any human tissue provided by the licensee, the CGO must **review all available information about the adverse reaction** to identify and remedy any errors, inadequacies or shortcomings in relation to the provision of the human tissue banking service.

Storage and distribution

Proper storage of human tissue to ensure safety and quality for clinical use.

1. The licensee must establish and implement an **inventory management system** that ensures the **biological and functional properties of all human tissues are preserved,** and the **risk of contamination is minimised.**

   a) Store or package every human tissue in a **validated container** that is appropriate for the intended use;

   b) Maintain and **periodically audit the inventory system;**

   c) Implement an appropriate labelling system to ensure that every human tissue is correctly identified and traceable from the time of its collection until the time it is distributed.

Storage and distribution

Proper storage of human tissue to ensure safety and quality for clinical use.

2. Store all tested/processed human tissue at **appropriate temperatures and storage periods** with regard to:
   a) The type of human tissue;
   b) The intended use of the human tissue;
   c) The packaging and processing requirements of the human tissue.
3. **Clearly label and segregate any human tissue that is under quarantine** from human tissue intended for distribution.
4. Clearly label any human tissue determined to be unsuitable for transplant or clinical use, and distribute it only in accordance with the donor's written consent and requirements of any other applicable written law^.
   a) The human tissue's non-suitability for transplant or clinical use;
   b) The purpose for which the human tissue is to be distributed for (e.g. research, education).

^Applicable legislative acts: MTERA, HOTA, HBRA

Storage and distribution

Proper distribution of human tissue to ensure safety and quality for clinical use.

All human tissues are **distributed** by the licensee such that the **biological and functional properties of the human tissues are preserved**, and the **risk of contamination is minimised.**

1. Package and transport the human tissue in a **validated container;**
2. 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 its custody;
3. Take appropriate measures to ensure the proper distribution of human tissue to the **intended recipient.**

Storage and distribution

Proper distribution of human tissue to ensure safety and quality for clinical use.

All human tissues are **distributed** by the licensee such that the **biological and functional properties of the human tissues are preserved**, and the **risk of contamination is minimised.**

4. An **instruction sheet** must accompany every human tissue distributed by the licensee which includes all of the following information:
   a) All the donor's screening results;
   b) The specific storage condition for the human tissue prior to its use;
   c) Any special requirement or measure that the medical practitioner must take to ensure the safe and effective use of the human tissue; and
   d) The measures that must be taken if there is any evidence of damage to or mislabelling of the human tissue or its packaging.

5. Establish and implement written procedures to **recall** the human tissue where its suitability is adversely affected, and notify any institution/person that receives that human tissue.

Storage and distribution

Proper distribution of human tissue to ensure safety and quality for clinical use.

All human tissues are **distributed** by the licensee such that the **biological and functional properties of the human tissues are preserved**, and the **risk of contamination is minimised.**

6. Licensee must distribute human tissue to the following persons, and only with expressed written consent by the donor and approval of the CGO:
   a) Another licensee; or
   b) A person licensed to provide a licensable healthcare service under the HCSA; or
   c) A person established overseas that is licensed to carry on the activities of a tissue bank or healthcare institution under the laws of that jurisdiction.

7. For any human tissue determined to be unsuitable for transplant or clinical use, distribute it only in accordance with the donor's written consent and requirements of any other applicable written law^.

^Applicable legislative acts: MTERA, HOTA, HBRA

[NEW] Re-identification and notification of donors in the event of incidental findings

Licensee must establish and implement a process for the following:

1. **To re-identify and inform a living donor** or **the authorized person (in the case of a deceased donor)** of any incidental or abnormal finding relating to the collected human tissue where prior consent has been obtained; and/or

2. **Inform the medical practitioner** caring for the living donor of any incidental or abnormal finding (where prior consent has been obtained).

Provision of information relating to human tissue distributed for transplant

1. For human tissue distributed for transplant purposes, the licensee must make available the following information **to a transplanting clinician**:
   a) The results of all screenings of the human tissue donor;
   b) The results of all tests conducted on the human tissue;
   c) Upon request, the medical history of the donor from whom the human tissue was collected;
   d) Upon request, the tissue bank's testing and processing information of the unit of human tissue.

2. After transplant, the licensee must obtain the following information **from the transplanting clinician** within such time as the CGO considers appropriate:
   a) Information concerning any adverse reaction arising from the transplant of the human tissue;
   b) Information about the recipient of the human tissue.

Outsourcing of tests

Requirements of outsourced service providers.

Licensee may appoint the following person(s) to conduct any test of human tissue that may be necessary for the provision of service:

Outsourced provider	Requirements
1. Another local tissue bank with the same tissue specialty	Licensed under the HCSA
2. Local clinical laboratory	Licensed under the HCSA
3. Foreign (overseas) tissue bank or clinical laboratory	Accredited, certified or licensed by any of the following organisations: a) American Association of Tissue Banks (AATB); b) Eye Bank Association of America (EBAA); c) Foundation for the Accreditation of Cellular Therapy (FACT). Any tissue bank or clinical laboratory operating outside Singapore which is approved by the Director.

Price transparency

1. A licensee must communicate all applicable charges (including administrative charges) to the donor or recipient:
   a) The charging principle is on a cost-recovery basis.

2. The donor or recipient's expressed written agreement to the applicable charges must be obtained before providing the human tissue banking service.

Quality Management Systems

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service.

The Quality Management System (QMS) shall encompass the following:

1. **Investigation** of any occurrence or complaint that discloses any **weakness or inadequacy affecting the quality of service;**
2. Identification and implementation of **appropriate actions to prevent a recurrence;**
3. Implementing **quality control measures for all human tissue** collected, processed and distributed, including measures pertaining to the safety and quality of human tissue in relation to:
   a) The recruitment of donors;
   b) The collection and transport of human tissue;
   c) The processing (including testing and quarantine) of human tissue; and
   d) The preservation, storage and distribution of human tissue.

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service.

4. Implement appropriate measures to **ensure the safety and health of donors** in relation to the collection of human tissue, including the detection and management of any finding or observation that has an adverse effect on the donors' health or safety.

5. Maintain **adequate and appropriate documentation** on the clinical outcomes of the transplant or clinical use of all human tissue, including any **adverse event** affecting any recipient that is or is believed to be attributable directly from the transplant or clinical use.

6. Implement **quality control measures** for tests performed and equipment used in the service.

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service.

7. Participate in regular **external quality assessment programmes** for each product qualification test, with the results reviewed by the CGO or a suitably qualified designee.
8. Implement a system that provides appropriate accountability and **delineates the roles and responsibilities of staff.**
9. **Conduct regular risk assessments** and **identify key performance indicators** in relation to service provision.
10. Update the QMS periodically and **review it at least annually** for effectiveness:
    a) Reports on QMS reviews are to be maintained.

Documentation

Documentation

Proper, accurate and complete records relating to all procedures and practices for human tissue banking activities.

Licensee must maintain **complete and accurate records** of all procedures and practices in relation to the service, and take all reasonable steps to **ensure the security** of all such records.

1. **Establish proper documentation control** of all policies, procedures and programmes:
   a) At least one or more appropriate personnel should be in-charge.
2. **Set out in procedure manuals** the service procedures and practices:
   a) All procedure manuals are approved, signed and dated by the CGO;
   b) All procedure manuals are regularly updated and made available to staff at all times.
3. Keep and maintain accurate records of every human tissue accepted into the processing facility.
4. Set out in written agreements the **terms of transfer** of any human tissue that is to be transferred to another licensee or qualified foreign facility.
5. **Validate and document** any changes to the procedures or equipment used before it is implemented.
6. Keep and maintain **accurate records of the CGO's approval** for the distribution and return of every human tissue.

Preserving Continuity of Care

[NEW] Continuity of operations

Ensure that all human tissue continues to be properly maintained.

1. Licensee must **establish a contingency plan** to ensure that the safety and quality of all human tissue in the licensee's custody are preserved in the event of any disruption to the licensee's operations.
2. The contingency plan must entail:
   a) Contracts or other arrangements for the **prompt restoration of the licensee's operations or the transfer** of human tissue within its custody to another licensee;
   b) Processes to inform the donor (where the human tissue was donated for autologous use) of any proposed transfer or disposal of human tissue as a result of operational disruption and to obtain the consent of said donor for any such transfer or disposal.

Annexes

The Schedule

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

List of Accredited Bodies for testing of Human Tissue

1. American Association of Tissue Banks (AATB)	
2. Eye Bank Association of America (EBAA)	
3. Foundation for the Accreditation of Cellular Therapy (FACT)	

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The End

Thank you

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