# GUIDELINES FOR MUSCULOSKELETAL BANKING

# COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION

This document was drafted during 2018 – 2021 and is intended to serve as guidance on the standard requirements of musculoskeletal tissue banking in South Africa. Amendments may be made in keeping with the knowledge which is current at the time of consideration.

**ACKNOWLEDGEMENTS:**

The South African Tissue Bank Association would like to thank and acknowledge the following individuals who contributed to the development of these guidelines:

**AUTHORS AND PARTICIPANTS:**

C Ndhlovu
M Steyn
S Venter
A Sterrenberg
T Nkontlha
M Labuschaigne
R Karakatsanis
H Heystek
R Chauke

**CONTRIBUTORS:**

Ms Lineo Motopi – Medical Scientist: Trauma, Violence, Emergency Medical Services and Forensic Pathology Services.

**TABLE OF CONTENTS:**

## 1. BACKGROUND AND PURPOSE

The purpose of these standards is to provide minimum criteria for the safe and effective management of musculoskeletal tissue banking activities in South Africa.

Musculoskeletal tissues can be procured from deceased heart-beating and non-heart-beating donors and from living donors (e.g. in the case of a patient undergoing hip or knee prosthesis surgery), and include bones, ligaments, tendons, meniscus, cartilage and other soft tissues (e.g. fascia lata).

The role of a functioning Tissue Bank is to recover, evaluate, process, store and supply suitable donor musculoskeletal tissues for the purpose of implantation and transplantation during tumour surgery, prosthesis replacement, as a bone void filler, repair of fractures, malunion, bone fusion (spine and limbs), ligament and meniscus replacement, maxilla-facial and periodontal surgery.

## 2. REFERENCES

*2.1 National Health Act 2003, chapter 8 and Regulation 182 Relating to Tissue Banks.*

*2.2 Department of Health – Standards of Practice for Acquiring, Packaging, Sealing, Labeling, Storage, Supply and Trans-shipment Of Human Tissue in South Africa, January 2004, Standard 9 & 16, 5.*

*2.3 Tissue banking – A Practical Guide, Dr. Graeme Pollock, pg. 2 and Table 1.*

*2.4 New York State – Department of Health, subpart 52-3, General Technical standards for Tissue Banks, December 2000, section 52-3.4.*

*2.5 The Tissue bank of Southern Australia – Procurement and Assessment of Tissue, April 2003.*

*2.6 United Kingdom Department of Health – Guidance on Microbiological Safety of Human Tissue and Organs Used in Transplantation, August 2000.*

*2.7 Canadian Standards Association – Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation, January 2003 – 5:6:2:1.*

## 3. TERMS AND DEFINITIONS

### 3.1. Agreement

3.1.1. **Agreement:** a contract, order, or understanding between two or more parties.

3.1.2. **Agreement review:** systematic activities carried out by two or more parties before finalising the agreement to ensure that requirements are adequately defined, free from ambiguity, documented and achievable by the supplier.

3.1.3. **Educational and promotional materials:** information made available by the musculoskeletal tissue facility to potential donors, patients and others.

3.1.4. **Informed consent:** a process of communication between a donor family and tissue coordinator, during which the donor family is provided with sufficient information to make

an informed decision, authorising retrieval or recovery of musculoskeletal tissue from the deceased donor.

3.1.5. **Obtaining materials and services:** evaluation of suppliers, qualifications of facilities and qualification of suppliers providing medical and bio-medical tests or services.

### 3.2. Deviations and non-conforming products or services

3.2.1. **Adverse event:** any adverse experience occurring at any dose or procedure that result in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or congenital anomaly /birth defect or required intervention to one of the outcomes listed in the definition.

3.2.2. **Adverse reaction:** (an adverse reaction is a type of adverse event). A noxious and unintended response to the musculoskeletal tissue implantation or transplantation of musculoskeletal tissue.

3.2.3. **Corrective action:** the action taken to eliminate the cause of a detected non-conformity or other undesirable situation to prevent or avoid its reoccurrence.

3.2.4. **Deviations:** departure from an agreed-upon course, design mean or method.

3.2.5. **Non-conformance:** failure to comply with specified requirements.

3.2.6. **Non-conforming product or service:** a product or service that does not satisfy one or more specified requirement.

3.2.7. **Preventive action:** an activity performed to eliminate the potential for non-conformance or other undesirable situations.

3.2.8. **Root cause analysis:** a technique used to identify the conditions that initiate the occurrence of an undesired activity or state.

### 3.3. Documents and records

3.3.1. **Documentation:** all written/medical documents that provide consistent information to ensure operational compliance and from a quality perspective that the requirements of these standards are met and maintained.

3.3.2. **Document control:** the control of the issue, use and review of authorized/approved documents within the Quality Management System.

3.3.3. **Electronic records:** information captured through electronic means and which may or may not have a paper record to back it up.

3.3.4. **Procedure:** a description of how an activity is to be performed.

3.3.5. **Quality records:** information captured in writing or electronically that provides objective evidence of activities that have been performed or results that have been achieved.

3.3.6. **Standard operating procedures (SOP):** this document describes operational methods aimed at the correct execution of a process in an established, logical, detailed and reproducible format.

### 3.4. Equipment

3.4.1. **Control of equipment:** the control, maintenance and monitoring of critical equipment.

3.4.2. **Equipment:** a durable item, instrument or device used in a process or procedure.

**3.5. Internal and external assessments**

3.5.1. **Audit/assessment:** systematic and independent examination aimed at verifying if activities performed and results rendered for quality purposes are in accordance as previously established, and to check if they are efficient and suitable for reaching objectives.

3.5.2. **External assessment:** an objective assessment of a facilities operation and performance by an external agency or external personnel.

3.5.3. **Internal assessment:** a systematic and independent examination of the Quality Management System and related activities by an internal assessment team to determine whether activities comply with appropriate standards, are implemented effectively and are appropriate to achieve defined objectives.

i. **compliance assessments:** evaluation of the system, its implementation and its effectiveness in ensuring products and services meet specified requirements.

ii. **system assessments:** evaluation of documentation and procedures.

iii. **vendor assessments:** evaluation of the effectiveness of the products or services procured.

**3.6 Organisation** (Facility)

3.6.1. **Emergency operation plans:** plans in case of disaster and other emergencies.

3.6.2. **Environmental monitoring:** policies, processes and procedures used for monitoring any or all of the following: temperature, humidity, oxygen saturation, noise levels, gas emissions, particulates and microbial contamination in a specific area. Where appropriate, the program must include sampling sites, frequency of sampling and investigative and corrective actions that should be followed when specified limits are exceeded.

3.6.3. **Facility:** a location where any activities relating to tissue recovery, evaluation, processing, storage and supply are performed.

3.6.4. **Good laboratory practice:** ensure that laboratory functions are carried out in accordance with regulatory requirements.

3.6.5. **Management:** senior personnel appointed to supervise and manage designated departments of a Tissue Bank.

3.6.6. **Quality assurance:** planned and systematic activities defined in a quality management system within the facility, to provide adequate confidence that tissue banking services meet relevant specifications and quality requirements.

3.6.7. **Quality control:** a systematic control of various factors that affect the quality of the product; intended to ensure that the manufactured product adheres to a defined set of quality criteria or meets the requirements of the customer.

3.6.8. **Quality management system:** a system including the establishment of a quality policy, quality objectives and the overseeing of all activities required to maintain the desired level of excellence and implementation of continual improvement.

3.6.9. **Quality objectives:** defined objectives and commitments pertaining to key elements of quality, such as fitness for use, performance, safety and dependability.

3.6.10. **Quality policy:** is a brief statement that aligns with the organization's purpose and strategic direction, provides a framework of quality objectives and includes a commitment to meet applicable requirements, as well as a continual improvement commitment**.** This policy must be consistent with other policies, within the organization. Management must take all necessary measures to ensure that its quality policy is understood, implemented and reviewed at all levels of the organization.

### 3.7. Process Control

3.7.1. **Accuracy:** the degree to which the measured value agrees with the true value of the measurement.

3.7.2. **Aseptic technique:** a practice designed to reduce the risk of microbial contamination of products, reagents, specimens or persons.

3.7.3. **Biological product deviation:** A deviation from applicable regulations, standards or established specifications that:

i. relate to the prevention of communicable disease transmission or tissue contamination;

ii. relate to an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to tissue contamination.

3.7.4. **Calibration:** a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument system or values represented by a material measure and the corresponding known values of a reference standard. Procedure that confirms under defined conditions, the relationship between values obtained from an instrument or system with those obtained using an appropriated certified standard. It may also include the adjustment activity.

3.7.5. **Change control:** a systematic approach to managing all changes made to a product or system.

3.7.6. **Clinical outcomes**: clinical data and outcomes of patients to be reviewed as part of quality program.

3.7.7. **Competency:** the ability to perform a specific procedure or task according to instruction and to produce consistent results with a specified accuracy. To be certified as trained to the appropriate task.

3.7.8. **Dehydration:** preservation of tissue using dehydrating substances.

3.7.9. **Donor:** A person who is the source of tissue for tissue banking purposes .

3.7.10. **Donor eligibility:** screening and testing of tissue donors for risk factors and evidence of communicable disease agents or disease against a documented donor selection criteria.

3.7.11. **Donor evaluation:** evaluation of tissue donors for risk factors and clinical evidence of relevant infectious disease agents or diseases for preventing the introduction, transmission and spread of infectious diseases. The donor family must agree to provide information related to the donor's biological, medical and social behavior. How donor evaluation should be performed (history, tests) and obtaining informed consent.

3.7.12. **Product evaluation:** inspections and tests required for tissue distribution.

3.7.13. **Ineligible donor:** a designation applied to a donor who is not acceptable as a donor for a specific reason, e.g. whose tissue may be at risk of transmitting an infectious disease as detected by testing and/or donor screening history.

3.7.14. **Label:** an inscription affixed to a product for identification and traceability.

3.7.15. **Lyophilization (freeze-drying)**: this consists of the removal of water, under vacuum conditions, from previously frozen tissue through a process of sublimation which consists in the direct passage from a solid phase (ice) to a gaseous phase (vapor) surpassing the liquid phase (water). Dehydration of the tissue impedes enzymatic activity and degeneration permitting preservation for long periods of time.

3.7.16. **Maintenance:** preventative maintenance is the care and servicing of equipment and facilities. It is the systematic inspection, detection and correction of incipient failures either before they occur or before the development into major defects.

3.7.17. **Microbial:** Involving infectious agents including bacterial and fungal organisms.

3.7.18. **Recovery:** the process that makes tissue available for transplant. It starts with the identification of a potential donor and ends with retrieval of the tissue from a living or deceased donor**.**

3.7.19. **Process:** a set of related tasks and activities that accomplishes a work goal.

3.7.20. **Process control:** designing and validating processes and procedures that affect the quality of tissue products and services in order to produce predictable outputs.

3.7.21. **Processing:** all operations tied to the preparation, modification, preservation and packaging of tissue destined for application on human patients.

3.7.22. **Quarantine:** the state of harvested tissues or tissue isolated during wait periods for data necessary to evaluate tissue suitability for transplantation or implantation.

3.7.23. **Sepsis:** systemic inflammatory response due to an infectious agent and accompanied by characteristic clinical and laboratory findings.

3.7.24. **Storage and preservation:** specifications on storage equipment required for preservation. Control of stored inventory. Preservation meaning suitable combination of conditions that preserves tissue quality during specified periods of storage.

3.7.25. **Traceability:** the ability to locate and identify tissue during each phase of recovery, processing, management, storage and distribution to the recipient or place of disposal, including the ability to identify the donor and the Tissue Bank that receives, processes and preserves the tissue and the ability to identify those responsible for the transplantation of tissue on recipients. Traceability includes the ability to locate and identify all pertinent data regarding products and materials that have been exposed to the tissue.

3.7.26. **Transport and shipping:** to and from the processing facility.

3.7.27. **Transplant physician:** the physician responsible for the implantation or transplantation of tissue into a recipient.

3.7.28. **Validation ("confirmation" or for equipment, environments and processes, "qualification"):** documented proof that assures, with a high level of certainty, that processes, devices or locations provided for a product correspond to predefined specifications and qualitative characteristics. A procedure is validated in order to evaluate if a system functions efficiently in relation to its foreseen purpose.

3.7.29. **Verification:** the process of evaluating objective evidence that a product, service or system meets specifications and that if fulfils its intended purpose.

**3.8. Process improvement**

3.8.1. **Conformance:** fulfilment of requirements.

3.8.2. **Corrective and preventative action plans:** plans to deal with non-conformances.

3.8.3. **Continuous improvement:** the actions taken to enhance the features and characteristics of products and or services and to increase the effectiveness and efficiency of the processes used to produce and deliver them.

3.8.4. **Continuous monitoring:** a mechanism that allows for surveillance of a process or system intended to ensure proper operation the detection of control exceptions.

**3.9. Resources**

3.9.1. **Competence:** ability of an individual to perform a specific task according to procedures evaluated on an on-going basis.

3.9.2. **Management responsibility:** the responsibility for and commitment to a quality management system belongs to the highest level of management. Quality management encompasses all activities of the overall management function that determines the quality

policy, objectives and responsibilities and implementation by means of quality planning, quality control, quality assurance and quality improvement within the quality management system.

3.9.3. **Resources:** the financial or productive factor required to accomplish an activity. Three basic resources are land, labour and capital; other resources include energy, entrepreneurship, information, expertise, management and time.

**3.10. Safety and facilities**

3.10.1. **Facilities and environmental controls:** monitoring requirements of laboratory and storage facility.

3.10.2. **Safety:** health and safety requirements of such a facility.

**3.11. Distribution**

Transportation and delivery of tissue for clinical use.

## 4. MANAGEMENT REQUIREMENTS

### 4.1 Organisation and structure

**4.1.1** The responsibility, authority and relationship of personnel performing, verifying or managing activities defined in this standard must be defined.

**4.1.2** The facility must have arrangements to ensure that commercial, financial and other pressures do not adversely affect the quality of the work of its personnel.

**4.1.3** The facility must be structured in such a way that confidence in its independence of judgement and integrity is maintained at all times.

**4.1.4 Executive Management:** the facility must define executive management. The executive management must have the responsibility and authority for the facility's operations, for appointing key personnel, which includes a quality representative or compliance officer, for performing management reviews and for compliance with these guidelines and applicable laws and regulations.

**4.1.5 Facility/Laboratory Principal:** the facility should be under the direction of a designated person/s with a degree in the health or natural sciences, qualified by training and/or experience and relevant continuous education for the specific musculoskeletal Tissue Bank services. The facility/laboratory principal must be responsible and accountable for ensuring that all operations are carried out properly and competently as required by the relevant laws and regulations. Should the facility/laboratory principal delegate these responsibilities to a designee, the facility/laboratory principal must retain ultimate responsibility.

**4.1.6 Medical Director:** the facility must have a medical director who is registered with The Health Professions Council of South Africa (HPCSA) and qualified by training and or experience in Tissue Banking Services. The medical director must have the responsibility and the authority for all medical matters related to the provision of musculoskeletal tissue for tissue banking products and related services. The medical director may delegate these responsibilities to another qualified medical professional; however, the medical director must retain ultimate responsibility for the delegated duties. Exceptions to procedures warranted by clinical situations must require justification and pre-approval by the medical director on a case-by-case basis. This deviation must be documented.

**4.1.7 Quality / Compliance Representative:** a designated individual must be appointed with overall responsibility for the quality within the facility. This individual must be responsible for establishing, implementing and maintaining of the quality management system. The quality representative must report directly to Executive Management. Nominated deputies must be defined in the absence of the quality/compliance manager.

## 4.2 Resources

The facility must identify and provide adequate staffing, materials, equipment and facility infrastructure to perform, verify and manage all activities covered by these Guidelines.

**4.2.1 Financial resources**: the facility must identify financial resource requirements adequate to perform, verify and manage its activities. The facility must develop a budget to ensure its on-going operation. The facility must undergo annual financial audits.

**4.2.2 Human resources**: the facility must have sufficient, trained, qualified and competent managerial and technical personnel to carry out their duties.

**4.2.3 Job descriptions**: Job descriptions must outline key responsibilities and duties to be performed and identify appropriate qualifications for each job position on the basis of education, training and/or experience.

**4.2.4 Training**: the facility must have a training policy and documented program to ensure all personnel are trained and competent to perform their assigned activities. The facility must have a system in place to identify training needs of staff. The qualifications of the trainers must be defined.

**4.2.5 Competence**: the facility must have a system in place to evaluate the competence of defined tasks and activities for all staff.

**4.2.6 Training records**: records must be kept of staff training and competency evaluations.

**4.2.7 Personnel identification**: records must be maintained of names, signatures, initials or other means of identification and inclusive dates of employment for all members of staff.

**4.2.8 Continuous education:** should be defined and requirements for continuous education must be met by all relevant employees.

## 4.3 Quality Manual

The quality manual must describe the quality management system and the structure of the documentation used in the quality management system. The quality manual must include or make reference to the supporting procedures including technical procedures. It must outline the structure of the documentation used in the quality management system. The roles and responsibilities of technical management and the quality manager, including their responsibilities for ensuring compliance with this guideline must be defined in the quality manual.

**4.3.1 Management review:** management must review and evaluate the quality management system at planned intervals and take action to ensure continued suitability, adequacy and effectiveness.

**4.3.2 Emergency operation plans:** the facility must have emergency operation plans to respond to the effects of disasters and other emergencies.

**4.3.3 Policies, processes and procedures:** the facility must develop and implement quality and operational policies, process and procedures to ensure the requirements of these guidelines are met.

### 4.4 Management Review

4.4.1 The facility management must review the quality management system at defined intervals to ensure its continued suitability and effectiveness and to introduce any changes or improvements.

4.4.2 The results of the review must be incorporated into a plan that includes goals, objectives and action plans.

4.4.3 The review must take into account, but not be limited to:

i. Follow-up of previous management reviews
ii. Status of corrective actions taken and required preventive action
iii. Reports from managerial and supervisory personnel
iv. The outcome of recent internal assessments
v. The outcome of external assessments
vi. The outcome of external quality assessments and other forms of inter-laboratory comparisons
vii. Any changes in the volume and type of work undertaken
viii. Feedback, including complaints and other relevant factors from clinicians, donors, patients and other parties
ix. Quality indicators for monitoring the facilities contribution to patient/donor care
x. Non-conformances
xi. Results of continuous improvement processes
xii. Evaluation of suppliers
xiii. Suitability of policies, processes and procedures
xiv. Corrective and preventive actions (trend analysis)
xv. Other relevant factors such as resources and staff training

### 4.5 Document Control

**4.5.1** The facility must establish, implement and maintain policies, processes and procedures to control all documents and information (from internal and external sources) that relate to the requirements of this guidelines. The document control system must address:

**4.5.2** The documents unique identification:

i. Title
ii. Edition or current revision date, or revision umber
iii. Number of pages
iv. Authority for issue

**4.5.3** The policies, processes and procedures must be in a standardised format.

**4.5.4** The documents must be uniquely identified, be current and dated to prevent the use of invalid or obsolete documents.

**4.5.5** The documents must be reviewed and approved by designated personnel prior to use.

**4.5.6** Invalid or obsolete documents must be removed from all points of use, or otherwise identified.

**4.5.7** Changes to procedures must be approved by designated personnel responsible for making the change and the nature of the change must be documented.

**4.5.8** If the facilities document control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments

must be defined, amendments must be clearly marked, initialed and dated and a revised document to be issued as soon as is practicable.

**4.5.9** The document control system must describe how changes to documents are maintained and controlled in an electronic system.

**4.5.10** The document control system must ensure that all appropriate documents are legible and readily accessible to personnel who rely on them to perform activities. Methods of copying/archiving must be defined.

### 4.6 Records

4.6.1 The facility must establish and maintain policies, processes and procedures for:

i. Record identification
ii. Procurement
iii. Accessing
iv. Traceability
v. Filing
vi. Storage
vii. Maintenance
viii. Disposition of records

4.6.2 Records must be legible, complete, retrievable and protected from damage.

4.6.3 The storage of records must be designed to prevent unauthorised access, copying, modification or destruction and ensure confidentially of records will be maintained.

4.6.4 The storage of records must ensure that there is traceability from source to final disposition, the environment is suitable and in a manner that prevents mix-ups, damage, deterioration and loss.

4.6.5 Records must be maintained to demonstrate products or services conform to specific requirements and that the quality system is effectively operated. Pertinent records from suppliers must be an element of this information.

4.6.6 The facility must establish and maintain appropriate processes for changes made to records. The date and identification of the person making the change must be recorded. Record changes must not obscure previously recorded information.

4.6.7 The records must identify the work performed, the person performing the activity and when it was performed.

4.6.8 Before destruction of the original records, copies of the records must be verified as containing the original content and must be legible, complete and accessible.

4.6.9 The facility must have policies and procedures that ensure the confidentiality of donors, employee and patient records.

4.6.10 Records must be reviewed for accuracy, completeness and compliance with relevant standards, laws and regulations.

4.6.11 The facility must have procedures to support the management of computer systems.

4.6.12 There must be a system in place for routine backup of all critical data and the backup data must be stored in an off- site location. The backup data must be protected from unauthorised access, damage, unintended destruction, loss or modification.

4.6.13 The facility must have a procedure in place to ensure electronic data is retrievable and usable and must be tested periodically.

4.6.14 Data integrity must be maintained.

4.6.15 Records to be maintained for 20 years.

### 4.7 Internal Assessments

4.7.1 The facility must perform internal assessments to verify that its operations comply with specified requirements.

4.7.2 The facility must establish, implement and maintain a documented assessment program for scheduling, conducting, documenting, reporting and reviewing internal assessments.

4.7.3 The internal assessment must be performed by trained and competent personnel, who are, wherever possible, independent of those activities being assessed.

4.7.4 When the assessment findings cast doubt on the correctness or validity of the activities being performed, the facility must take immediate corrective action and must notify the affected parties in writing.

4.7.5 Internal assessment results must be reviewed by personnel responsible for the area assessed, evaluated to determine the need for corrective and preventive action, communicated to appropriate staff and reported to executive management.

4.7.6 Additional or unscheduled internal assessment must be performed where the identification of non-conforming activities or departures from authorised procedures cast doubt on the compliance of activities being carried out by the facility. The facility must ensure that the appropriate areas of concern are audited as soon as possible.

### 4.8 Non-conformances, Corrective and Preventive Actions

4.8.1 The facility must have a procedure to detect, capture, investigate, assess, monitor and report deviations from accepted policies, processes, procedures and acceptable standards or criteria.

i. The deviation must be reported as soon as it is identified
ii. Deviations having the potential to affect the safety, purity or potency of a product; donor safety; employee safety or the safety of a patient, must be evaluated by an individual qualified to approve the release of the product. This approval must be given by the medical director, and/or the patient's doctor, depending on the circumstances.

4.8.2 **Corrective action**: the facility must have procedures for corrective action of non-conformances, complaints and incidents and must include the following:

i. A description of the non-conformance
ii. Personnel responsible for the resolution of the non- conformance
iii. Investigation of the root cause
iv. The medical significance of the non-conformance considered and where appropriate, the relevant parties informed
v. Determination of the corrective action
vi. Implementation of the corrective action
vii. Monitor and verification of the effectiveness of the corrective action
viii. Review of non-conformances to detect trends

4.8.3 **Preventive action:** the facility must have systems in place to identify areas of improvements and potential sources of non-conformities, either technical or concerning the quality system. Where preventive actions are required, action plans must be developed, implemented, monitored and verified to reduce the likelihood of the re-occurrence of such non-conformances and to take advantage of the opportunity for improvement.

4.8.4 **Customer notification:** the facility must report to the customer as soon as possible, any musculoskeletal tissue products lost, damaged or otherwise unsuitable for use or any released products or delivered services determined to be non-conforming.

4.8.5 The facility must establish and maintain policies, processes and procedures to prevent the unintended use or release of non-conforming material, segregation and disposal.

4.8.6 The facility must define the responsibility for the review and authority for the disposition of non-conforming products.

### 4.9 Agreements

4.9.1 The facility must establish, implement and maintain policies, processes and procedures for developing, approving and reviewing agreements.

4.9.2 Prior to the acceptance of a verbal or written agreement, the agreement must be reviewed by the facility to ensure:

i. The customer's requirements are adequately defined, documented and understood

ii. Any differences between the agreement requirements and the facilities services and products offered under the agreement must be resolved

iii. The facility has the capability and resources to meet the agreement requirements

iv. The facility must define how changes to agreements are made and communicated to affected parties

4.9.3 Records of reviews, including any significant changes and pertinent discussions must be maintained.

4.9.4 The review must include work referred to a subcontractor.

4.9.5 Customers must be informed of any deviation from the agreement.

4.9.6 If an agreement needs to be amended after acceptance, the same agreement review process must be repeated and any amendments must be communicated to all affected parties.

4.9.7 **Records:** the responsibility of each facility involved in the recovery, processing, storage or distribution of tissue to provide a copy of all the relevant records upon request to other authorised entities.

4.9.8 **Informed consent:** the informed consent documents must be reviewed and approved by the medical director.

4.9.9 **Education and promotional material:** the facility must maintain records justifying claims made in its educational and promotional material provided to potential donors, recipients and medical professions. The therapeutic and scientific claims must be reviewed and approved by the medical director.

### 4.10 Informed Consent

4.10.1 The informed consent must include a comprehensive explanation, in understandable terms to the consenter(s), of any applicable benefits, risks, discomforts and alternatives relating to the collection, storage, processing and distribution of the musculoskeletal tissue products. Matters relating to traceability, data protection, and confidentiality should also be addressed. In addition to conforming to relevant laws and regulations, informed consent should, amongst others, refer to the following:

i. A description of the participant.

ii. The consenter(s) must acknowledge in writing that he or she has received information concerning the benefits, risks, discomforts and alternative musculoskeletal tissue

donation methods, that he or she has had an opportunity to have access to donor advocacy services and that he or she has been given the opportunity to ask questions and had those questions answered satisfactorily.

iii. The informed consent requirements and regulations that apply to donors who are non-competent persons or persons who may temporarily lack decisional capacity must be met.

iv. The consenter(s) must have the opportunity to deny or withdraw consent to the recovery procedures without affecting his or her access to medical care.

v. Where relevant, an explanation of the application of the anonymity principle in the case of altruistic donation should be provided.

vi. Relevant data protection laws and regulations aimed at protecting the confidentiality of, access to and the processing of personal information relating to the consenter(s).

**4.11 External Services and Supplies**

4.11.1 The facility must have policies, processes and procedures to ensure that the selection, qualification, procurement receipt, handling, storage and utilisation of all materials used in the processing of musculoskeletal tissue products, conform to specified internal requirements. Critical materials must be identified and traceable.

4.11.2 The facility must receive, inspect and keep record of all materials that come into contact with the musculoskeletal tissue product or that directly affect the quality of a musculoskeletal tissue product, prior to acceptance or use.

4.11.3 Records of the following to be maintained:

i. Identification of the material
ii. Name of the manufacturer
iii. Lot number and quantity
iv. Date of receipt
v. Date of manufacture and/or expiration date
vi. Results of visual inspection upon receipt (if applicable)
vii. Indication of acceptance or rejection
viii. Certificate of analysis or manufacturer's insert (if applicable)
ix. Manufacturer's instructions, including recall or defect notices, advisories and other such as material data sheets (MDS)

4.11.4 Materials must be stored according to manufacturer's instructions.

4.11.5 The facility must maintain an inventory management system.

4.11.6 Reagents prepared by the facility must be appropriately labelled and standardised to meet or exceed specifications. Results of tests performed on reagents must be documented.

4.11.7 The facility must have a procedure in place for the selection of services and supplies that it uses and that affect the quality of the musculoskeletal tissue product. The facility must evaluate suppliers of critical supplies and services which affect the musculoskeletal tissue products. Records of these evaluations must be maintained.

4.11.8 The facility must maintain a list of approved suppliers for critical items and the list must be reviewed at defined intervals.

4.11.9 When material is to be used in an emergency (prior to inspection), the material must be identified to permit recall and quarantine of associated products.

4.11.10 Materials that come into contact with the musculoskeletal tissue product must be sterile and of appropriate grade for intended use.

### 4.12 Subcontracting

4.12.1 When the facility subcontracts work, the facility must provide evidence that the subcontractors' experience and technical competence comply with appropriate standards and legislations.

4.12.2 The facility must evaluate and select sub-contractors on the basis of their ability to meet specific technical and quality assurance requirements.

4.12.3 The facility must maintain a register of all subcontractors, including the scope of subcontracting, records of the competence assessments and review the records of approved sub-contractors.

4.12.4 The facility must maintain up to date contracts and agreements with sub-contractors.

### 4.13 Management of Complaints

4.13.1 The facility must have a policy and procedure in place for the resolution of complaints or any other feedback received.

4.13.2 Records must be maintained of all complaints, investigations and corrective actions taken by the facility.

### 4.14 Continuous Improvement

4.14.1 The facility must continuously improve the effectiveness of its quality management system in order to identify any potential sources of nonconformity or other opportunities for improvement. Action plans for improvement must be developed, documented and implemented.

## 5. DONOR SELECTION

To ensure that all musculoskeletal tissue recovered are of an optimal quality to maximize the successful outcome of the application and prevent the transmission of disease to the recipient.

### 5.1 Age

The recommended donor age is between 16 and 80 years for bone.
The recommended age of donation for tendons and ligaments is between 16 and 65 years.
The recommended age for costochondral cartilage is between 16 and 55.

### 5.2 Hemodilution Assessment

Information on blood transfusions during the hospital stay shall be obtained from the nursing staff, if possible and submitted to the medical director for review and approval for recovery.

### 5.3 Expression of Willingness to make Cadaveric Donation

The next of kin signing consent must be adequately informed of all aspects relative to the donation and retrieval process.

### 5.4 Consent for Retrieval from a Living Donor

The person responsible for overseeing the donation process must endeavor to supply adequate information to the donor concerning all the aspects relative to donation and the retrieval process before actually donating. Information must be provided by trained personnel capable of

communicating in a clear and adequate manner while responding to all of the donor's questions. Information shall include; aims and nature of recovery, risks and consequences, recording and protection of donor's personal information, and medical confidentiality.

Donors have the right to be informed of the results of tests performed to exclude the risk of any communicable infectious diseases. The mode of communicating any possible positive results must be established. Donors must be guaranteed confidentiality for the use of their information.

### 5.5 Documenting Expressed Will

The expression of the intent to make a cadaveric donation must be documented along with the purposes for which tissues may be used (including therapeutic use, clinical experimentation, research or both) and any specific instruction relative to disposal if the tissues are not used for the purposes for which they were designated. All applicable laws and regulations must be adhered to in relation to the application.

### 5.6 Confidentiality

Documents and information relative to the donor are confidential and shall be stored and treated with respect to privacy for the donor and his/her family. Anonymity is guaranteed using identification codes to track tissues. Strict confidentiality must be observed by all employees of the tissue bank with regard to all information pertaining to tissue donors and recipients in whose treatment the bank is involved.

### 5.7 General Donor Eligibility

A person's eligibility to donate tissue should be based on their medical and behavioral history, clinical state, physical exam, results of serological tests and microbiological screening, performed with the goal of reducing the risk of transmitting pathologies from the donor to the recipient.

#### 5.7.1 Assessing Donor's General Eligibility

i. An extensive collection of information regarding the potential donor's medical, behavioral and sexual history must be gathered by competent personnel.
ii. If the actual person responsible for selecting donors is not part of the tissue bank staff, there must be written agreements on procedures to follow regarding donor assessment and the types of tissue and blood samples to retrieve in compliance with these present guidelines.
iii. Questions regarding medical history posed in the form of a questionnaire or interview shall be directed to the donor if he/she is living. Otherwise, questions will be directed to their next of kin, presiding physician, general practitioner or other reliable source, in case of cadaveric donation.
iv. Information from medical records and results of exams and lab tests must also be taken into consideration. All documentation must also indicate the source of information. Living donors must confirm the veracity of all information given.

#### 5.7.2 Exclusion Criteria for an Ineligible Donor

The following conditions are cause for total exclusion for tissue use:

i. unknown cause of death for cadaveric donors (tissue may be used for transplantation only after an autopsy has pinpointed the cause of death and/or the following points have been excluded)

ii. disease of unknown etiology
iii. personal history or clinical or laboratory evidence of an active infectious disease including HIV, HBV, HCV or unknown etiology of jaundice
iv. hemophilic persons who went through infusion of coagulation factors of human origin
v. persons in hemodialysis (longer than one month) for chronic kidney failure
vi. systemic infections that have not been checked at the time of donation, including bacterial diseases, systemic viral infections, fungal or parasitic diseases, or serious local infections of tissue destined for donation
vii. donors suffering from bacterial septicemia may be evaluated and taken into consideration for donating ocular tissue, only if it is to be preserved with the means of identifying any possible contamination
viii. persons with risk factors for Creutzfeldt-Jakob disease or variant thereof
ix. presence of chronic degenerative neurological diseases of unknown etiology (e.g. Alzheimer's disease, multiple sclerosis, amyotrophic lateral sclerosis, acute sclerosing panencephalitis, Parkinson's disease, progressive multifocal leukoencephalitis) will be reviewed by Medical Director for approval or be declined.
x. persons who have used derivatives of hypophysary hormones or allotransplantation of the dura mater or have undergone unspecified intracranial procedures
xi. active or previous malignant neoplasm with exceptions for brain cancer
xii. subjects who have undergone xenotransplantation are excluded
xiii. ingestion or exposure to toxic substances that may be transmitted in harmful doses (e.g. cyanide, lead, mercury, gold)
xiv. pharmacological treatments with immunosuppressants which may render tests unreliable for viral markers
xv. chemotherapy or radiation therapy
xvi. autoimmune diseases including collagen diseases that may compromise tissue quality
xvii. vaccination with a live virus (measles, rubella, mumps, varicella, yellow fever, smallpox, covid 19) within the four weeks preceding donation
xviii. risk of transmitting infectious diseases related to travelling or exposure to infectious agents, which are not excludable with extensive testing
xix. haemopoietic disorders including: monoclonal gammopathy (MGUS are not included in the exclusion criteria, with the exception of bone tissue, unless this latter undergoes processing (lyophilization and demineralization) to eliminate the haemopoietic cells), myelodysplasia, polycythemia vera and essential thrombocythemia
xx. Any animal bite in the past 12 months where donor received a tetanus shot
xxi. Active Infections:
Acquired immunodeficiency syndrome (AIDS)
High risk for HIV infection
Viral Hepatitis (B or C)
Human immunodefiency virus (HIV)
Active septicemia (bacterial, fungal or viral infection).

### 5.7.3 Assessing donation from minors (between 16 and 18 years of age)

The criteria listed in the previous section, applies.

## 6. CONSENT FOR DONATION

Informed consent including telephonic/verbal consent must be obtained from the donor and/or next of kin and must be followed-up with written confirmation within 48 hours.
All consents must be witnessed and co-signed by two witnesses.
Should consent be given for donation, the consent document must be completed and returned to the relevant Tissue bank.

## 7. PHYSICAL ASSESSMENT

Before recovery, the deceased donor must undergo accurate physical examination.
Particular attention must be paid to the presence of:

i. venereal infections (genital ulcers, anal condylomas, etc.)
ii. signs of infective risk factors (punctured blood vessels, tattoos, piercing)
iii. cutaneous infections, dermatitis, local inflammatory skin infections, ectoparasitosis
iv. fractures, avulsions, lacerations or abrasions that may contaminate or compromise the integrity of tissue to be recovered
v. internal trauma that can cause cross contamination between cavities (e.g. injury to the bowel)
vi. dirt/filth found on the body that can relate to an increased risk for contamination/cross contamination
vii. oral thrush, blue and purple spots consistent with Kaposi sarcoma.

If signs are present upon examination that might indicate exclusion criteria for donation, further in-depth examination of medical history and adequate laboratory or instrumental tests must be performed in order to exclude the presence of contraindications to donation.

### 7.1 Tests for Communicable Diseases

i. Potential donors must be tested in relation to communicable diseases in compliance with this document.
ii. Tests must be carried out on blood and tissue samples from the donor.
iii. In case of cadaveric donation, all blood samples must be obtained as quickly as possible, in order to reduce the degree of hemolysis within the sample.
iv. Blood samples must be adequately identified and labelled.
v. If blood is drawn from a living donor or a cadaveric donor with heartbeat, samples must not be taken in proximity to active infusion sites.
vi. If the donor has experienced significant loss of blood and has undergone blood transfusions, hemo-components or infusion of plasma-expanders in the 48 hours prior to blood being drawn; results must be evaluated taking into account hemodilution.
vii. For living donors, blood samples are taken at the same time as the donation, or within an allowable margin of 7 days after the donation.

## 8. DONOR DOCUMENTATION

There must be an appropriate donor information file for every donor that includes the applicable:

i. personal information (name, surname, date and place of birth)
ii. age, sex, medical history and behavioral history (information gathered must be sufficient enough to compare with exclusion criteria when necessary)
iii. results of physical examination
iv. formula for hemodilution, if applicable
v. consent form

vi. clinical data, results of serology and microbiology tests and results of any other additional tests that may have been done
vii. if necroscopic examinations have been performed and results are available, these can be included.

## 9. TISSUERECOVERY

### 9.1 Personnel

Recovery is to be performed by personnel who have completed a training program provided by a specialized medical team or by the Tissue Bank.
These trained technicians shall undergo regular monitoring and assessment of their professional skills.

### 9.2 Protocol and Procedures

The Tissue Bank must define protocol for the recovery of tissues and written agreements must be established including protocol to be used, if the medical team is not employed by the Bank. This must be done for all types of tissues or samples to be retrieved.

Procedures must include verification of the following:

i. donor's identity
ii. documentation relative to consent/expression of will
iii. evaluation of selection criteria for donors
iv. evaluation of lab tests

Procedures for recovery, packaging, labelling and transportation of tissues to the Bank must also be specified.

### 9.3 Procurement Facilities and Quality Procedures

Facilities where recovery is performed must be acceptable including good ventilation, light, water and work space.

Recovery shall be conducted in accordance with tissue bank operating procedures to ensure tissue extraction takes place in reasonably clean environments, in order to safeguard tissue properties and reduce the risk of bacterial contamination.

### 9.4 Donor Identification

Before recovery of the deceased donor, the retrieval officer must verify the identity of the donor. A record must also be kept of the procedures used for verification including identification of personnel performing such procedures.

The retrieval officer must also certify that all donor exclusion criteria have been cleared and legal consent documents to express the will to donate have been signed.

After all tissues have been recovered from deceased donors, the body should be carefully reconstructed.

### 9.5 Time Limits for Recovery

Recovery must be performed as soon as possible following death. Blood and soft tissues samples must be procured before or during recovery. If the body is cooled within the first 6 hours after death, retrieval may be performed within 5 days.

The name of the recovery facility and the length of time passed between death and retrieval, must be included in documentation sent to the Tissue Bank.

**9.6 Recovery Process**

To ensure the proficient removal of tissue to minimize the chance of rejection, infection or non-use of the tissue, techniques appropriate to specific tissue recovered should be utilized.

Standard operating procedures set up within specific tissue banks must be adhered to in order to minimize infection and cross contamination of tissue.

## 10. QUARANTINE OF TISSUE

i. The tissue will be allocated a unique donor number and placed in quarantine until all tests are completed.
ii. Tissue shall be quarantined immediately after procurement and shall remain segregated until it is deemed suitable for use.
iii. A quarantine area shall be established in the medical fridge/freezer. This area should be a sealable unit or access controlled room.

    It must be clearly marked QUARANTINE.

    Immediately after recovery, all tissue shall be placed in the quarantine area of the medical fridge/freezer.

    No tissue may be released from this area until:

    All serology and microbial testing have been completed and found to be negative.
iv. Once tissue has been cleared for processing, it may be moved to the main processing storage area of the fridge.
v. Should tissue not be deemed suitable for processing, it will remain in the quarantine area until such time as steps are taken for the disposal of such tissue.

Any additional requirements to the quarantine process will be determined by the tissue bank's standard operating procedures.

## 11. DISPOSAL OF CONTAMINATED TISSUE

To ensure the safe and secure disposal of non-usable tissue and to prevent contamination of other tissue, the processing environment or personnel.

i. Tissue that has deemed not fit for transplant use is identified and labelled accordingly.
ii. The label must not interfere with the ready inspection of the contents of the containers.
iii. The tissue is then placed in an anatomical waste container and transferred to the relevant licensed discard institution.
iv. Receipt of the tissue by the discard institution must be signed for to acknowledge receipt and a destruction certificate must be obtained.

## 12. LABORATORY ANALYSIS

If possible, tests must be performed in a routine manner, by an authorized laboratory accredited by the relevant bodies such as SANAS (South African National Accreditation System). Tests used must be validated for compliance with current scientific knowledge.

## 13. STORAGE RETENTION BLOOD/TISSUE SAMPLES

The reserved blood serum and/or tissue samples of all donors must be accurately identified and must be adequately sealed and preserved at a temperature less than -40˚C for at least 20 years after utilization of the tissue.

## 14. SEROLOGY SCREENING

Donors are considered ineligible for donation and their tissue cannot be used for transplantation if they test positive for any of the following conditions:

i. Human Immuno Deficiency Virus
ii. Hepatitis C
iii. Hepatitis B
iv. Syphilis

Should a positive blood test be reported, further testing must be carried out, provided blood is available. Further specific tests may also be required in cases where the donor comes from geographical areas where other infectious diseases are endemic.

This repeat or additional test should be done on the same blood sample using an alternative test of equal or greater sensitivity, and if possible, using a different facility.

**Follow-up for Living Donors:**

In cases of requests of test results confirmation, for HIV 1 and 2, HCV and HbsAg, tests can be repeated on living donors at least 180 days after donation. Alternatively, the blood sample taken at the time of donation or following the donation must be tested with nucleic acid amplification tests (NAT) for HIV, HBV and HCV.

The results of these tests must be available before tissue can be released.

**Serological Reports:**

Serological and bio-molecular reports must remain attached to the donor's documentation.

## 15. PROCESSING FACILITIES

When certain activities include the processing of tissues that come into contact with the environment, they must be performed in a location that assures a specific type of air quality and filtration in order to minimize the risks of contamination, including contamination among donations. The efficacy of these measures must be validated and controlled.

It is necessary to document and, hence, be able to demonstrate that the selected environment complies with quality and safety requirements. The processing environments and laminar flow hoods must be classified, updated and monitored

Entrance to processing rooms must be rigorously limited to persons directly involved or to authorized visitors and must be accompanied by internal personnel. Entry must be preceded by dressing in specific garments that minimize contamination from external sources and protect personal safety.

Procedures for cleaning and sanitizing rooms must be validated and include an adequate rotation of decontaminating cleaning products.

Plans for routine and periodic detailed cleaning procedures must be defined and cleaning personnel must be adequately trained. Cleaning activities must be recorded including identification of the personnel responsible.

Sanitizing and decontamination procedures must be validated for all of the different types of tissues that may be processed within the same processing room.

## 16. STORAGE FACILITIES

If tissue must be preserved, storage conditions necessary for maintaining required tissue properties must be defined. Critical parameters must be controlled and monitored.

Refrigeration devices and incubators containing tissues must be fit for the use envisaged, and appropriate monitoring procedures of such devices must be adopted to ensure that the tissues are maintained at the desired preservation temperature. Continuous temperature monitoring and recording, together with effective alarm systems must be put in place in all incubators, refrigerators, storage freezers and liquid nitrogen tanks in order to signal any circumstance in which conditions come close to or fall outside the predefined ranges.
Storage areas must be organized where tissue is clearly separated and distinguishable from those that are quarantined, those suitable for processing and those that must be discarded.

## 17. EQUIPMENT

The arrangement and maintenance of all equipment and the use and preservation of materials must correspond to their intended purpose and minimize every risk for recipients and/or personnel.

All critical technical equipment and devices must be identified, validated and periodically inspected and must preventatively undergo maintenance in compliance with the manufacturer's instructions. The equipment management system is put in place to ensure that equipment characteristics and reliability remain unaltered over time.

Equipment or materials that affect critical phases of processing or storage (e.g. temperature, pressure, number of particles, level of microbial contamination) must be identified and kept under observation, monitored, have alarms checked and undergo adequate revision and repair to identify any malfunction or defects and assure critical parameters constantly remain within acceptable limits. When possible, all equipment that has a critical function must be calibrated to certain reference parameters.

All equipment and instruments providing critical measurement functions must be calibrated to a specific reference parameter, where this is available. A maintenance plan must therefore be established listing all critical plant/equipment/systems and the specific checks to be carried out.

New or repaired equipment must be checked during installation and validated before use. The results of all inspections must be documented.

All equipment considered critical needs to periodically receive maintenance, be cleaned, and disinfected. Each piece of critical equipment needs to be equipped with a reference manual, including its function in compliance with regulation, along with detailed instructions on methods of intervention in case of malfunction or breakdown.

**Waste Disposal**

Hazardous waste must be collected with methods that minimize risks for the Tissue Bank's personnel and the environment and must be consistent with national and local regulations.

## 18. QUALITY CONTROL

Serology and microbiology screening tests are part of quality control maintenance.

All test results from the laboratory shall be received in writing.

The blood test results finally issued by the laboratory should either be positive or negative.

**Microbiology tests**

Tissue samples must be tested prior to processing and after processing to determine the possibilities of cross contamination.

The MCS test results should read:

i. Microscopy: Pus cells – Absent, mild or moderate. Bacteria – "Result".
ii. Aerobic Culture – "No Growth".
iii. Fungal Culture – "No Growth".

## 19. TISSUE RELEASE

All tests results must be deemed negative and all documentation must be checked and verified by the medical director prior to release.

## 20. PACKAGING AND LABELLING

The tissue must be packed and labelled in an environmentally controlled facility with a traceable unique number/coding.

The minimum requirements of information on labelling:

i. Product description
ii. Product code
iii. Storage temperature
iv. Expiry date
v. Dimensions
vi. Preservation medium

vii. Traceability Number

## 21. DISTRIBUTION OF TISSUE

Distribution of tissue should be free, fair and equitable, regardless of gender, race, creed, religious beliefs, financial status, political beliefs or affiliation to South African citizens or permanent residents, and other allowed geographical regions. The distribution shall be objective and transparent and shall be based purely on clinical needs.

Records must be maintained of all hospitals, clinics and /or medical professionals to whom the tissue is distributed.

## 22. EXTERNAL COLLABORATIONS

If the Tissue Bank is not equipped with all organizational needs and laboratory equipment necessary for optimal processing, packaging and distribution of tissue which allow for the best clinical use possible, it may refer to external facilities that adhere to applicable regulations for certain procedures, but not the entire process.

Referring to these facilities may also be indispensable in times of temporary malfunction in which the Tissue Bank itself cannot conduct all necessary operations. These types of collaborations shall be regulated by written agreements or contracts that specify the responsibilities expected of the external facility and list all relative procedures in detail.

Tissue Banks shall evaluate and select external facilities based on their abilities to respect these guidelines.

## 23. ADVERSE EVENT

Any unintended, unexpected or untoward medical occurrence that may be consequent or related to tissues that are transplanted/implanted. An adverse event may also be considered to be an incident or a reaction that:

i. Results in in-patient hospitalization;
ii. Results in prolonged hospitalization;
iii. Results in persistent or significant incapability (including transmission of disease or failure of the transplant tissue function or integrity);
iv. Results in death of the recipient.

If the error or accident is not detected prior to the distribution of tissue, the error or incident shall be reported immediately to the receiving facility/s.

The medical director must be informed within 24 hours of a report of an adverse event.

All correlated data relating to the event must be documented and send to the medical director, within 7 days of discovery, including:

i. Unique donor number;
ii. Time, date and cause of death of donor (if applicable);

iii. Time, date and place of tissue recovery;
iv. Type of tissue recovered;
v. Name of person/s recovering such tissue;
vi. Donor serology report;
vii. Recipient name;
viii. Recipient Surgeon performing the procedure;
ix. Date of procedure;
x. Hospital details where procedure was performed;
xi. Details of any untoward events preceding, during or immediately after surgery;
xii. Details of adverse event
xiii. Sterilization records

Written notice of such event shall follow this notification, specifying the unique donor number and type of tissue believed to be affected, naming the infectious or transmittable agent or detailing the compromise of integrity.

The written report shall be forwarded to the Medical Director within 7 days. The findings of the report will determine the possible recall of products.

The Medical Director shall report his findings of this report to the relevant Tissue Bank and inform the Director General of the National Department of health of such Adverse Event.

An entry must be made in the Tissue Bank's Adverse Event Register.

## 24. PROTECTION OF THE RECIPIENT

Tissue and tissue products must only be released for recipient use when all required tests have been satisfactorily completed, documented and all records of the tissue or tissue products reviewed for conformance to specified requirements according to the standards of practice.

## 25. TRANSPORTATION OF TISSUE

Depending on the method of processing, the storage temperature must be maintained.

The insulated container must be well marked with:

i. Biological material: Handle with Care
ii. Human tissue
iii. Address and contact details of the receiving person/s
iv. Storage instructions for the Receiving Facility.
v. Relevant Tissue Bank details
vi. The receiving person shall be informed of the estimated time of arrival of the tissue and the correct storage conditions in which to transfer the tissue.

## 26. CONFIDENTIALITY

According to the terms of the National Health Act No 61 of 2003, donor and recipient confidentiality shall be maintained, according to prescribed laws and regulations

### 26.1 Donor

i. Ensure that the donors' identity remains confidential in terms of the above act.
ii. Ensure that the donors' medical conditions remain confidential (especially in regard to HIV status).
iii. In cases where HIV testing is positive and in line with individual tissue bank policy, the living donors should be given an opportunity to decide whether they would like to know the outcome.

### 26.2 Recipient

i. Ensure the privacy of the recipient details in terms of all applicable laws and regulations.
ii. Ensure that no statements are made to the public in which the recipient may be identified unless written permission is received from the recipient for this disclosure.

## 27. RECORD KEEPING

In accordance with the National Health Act 2003 and the Department of Health Standards for Practice (January 2004), accurate records must be kept.

These comprehensive records will protect all participating parties against any legal claims should they arise.

All records must be kept in a safe, secure place where they are reasonably protected against theft, damage and/or fire.

All medical records shall be kept for 20 years.

## 28. QUALITY MANAGEMENT SYSTEM

The Tissue Bank must implement and maintain a documented system for quality management. A compliance officer or quality management representative or responsible person must also be appointed who is not directly involved in the processing of tissue.

The responsible person must assure that all activities comply with legal requirements, the present guidelines and the institution's Quality Management System manual.

The Quality Management System is comprised of a manual, policies and standard operating procedures (SOP), which describe all critical activities. Furthermore, it includes all other documentation that describes personnel training, management of instruments/devices, and qualifications for the workplace, and must include records of all actions and provide evidence of activities performed.

Procedures must guarantee standardization of activities performed and traceability in all phases: coding, donor eligibility, supply, processing, preservation, storage, transportation, distribution and disposal, including all aspects of quality control and assurance.

Documentation and procedures must be periodically audited and updated to comply with any modifications to activities or norms and legal requirements. All modifications must be audited, dated, approved, documented and performed by identified personnel.

Documents must be organized in such a manner that chronology of modifications can be easily provided

and assures that only the latest updates are in use.

Copies of manuals and procedures must be made available for all personnel and, upon request, for any persons authorized to inspect the Tissue Bank.

The Tissue Bank must organize a system of checking its own activities aimed at certifying the observation of procedures and regulation in order to assure constant, systematic and improved progress.

**28.1 Documentation**

All documentation must be confidential, accurate and complete.

All documents must be legible and indelible. They may be handwritten or typed using a validated system, including electronic support, in which case all security measures must be taken against external access and possible attacks by viruses. Furthermore, backup procedures must be performed to avoid the loss of any data, performed both daily and periodically.

The execution of each procedural phase (recovery, preparation, lab testing, storage and distribution) must be documented so that each step may be clearly traceable, as well as identification of the person who performed the work, including information on all relevant departments. Moreover, documentation must show the results of tests, as well as all related interpretations and all data regarding the products or materials that come into contact with the tissue. Materials, devices and personnel involved in all critical activity must be identified and recorded.

Documentation must be detailed so that each step performed may be clearly understood and must be made available upon request for inspection by authorized persons within limits regarding medical-legal confidentiality. Access to documentation and data must be limited to subjects authorized by the supervisor, as well as any appropriate authorities who perform inspections.

All documentation regarding donor history and information on tissue processing must be made available upon request by the transplant surgeon, with exception of any information that infringes upon the donor's confidentiality.

**28.2 Traceability**

Each musculoskeletal recovery must be assigned a unique number, which is used to identify the tissue throughout all phases from retrieval to distribution and use. The initial and unique number must match the tissue with its donor.

**28.3 Data Protection and Confidentiality**

All necessary measures must be adopted to ensure that all data collected and any access by third parties, remains anonymous so that neither the donor nor the recipient are identifiable.
Data protection and safeguarding measures must be adopted to prevent addition to, elimination of or unauthorized modification of stored information regarding donors and any other transfer of information.

No information must be divulged that leads to donor identification without authorization. The identity of recipients must not be revealed to the donor or his/her family and vice versa. Access to documents must be limited to subjects authorized by the Tissue Bank as well as appropriate authorities in case of inspection and must comply with confidentiality measures.

### 28.4 Archives

All records critical to quality and safety must be archived for at least 20 years after the tissue's use, disposal or expiry.

All documentation regarding tissue that has not been processed must also be archived for 20 years.

### 28.5 Protecting the Health and Safety of Personnel

It is the responsibility of the Tissue Bank to assure that compliance with all relevant and related regulations and laws is enforced in order to protect the health and safety of personnel.

Procedures on how to maintain a safe workplace must be present. Inherent risks due to the use and manipulation of biological materials must be identified and reduced as much as possible while maintaining an adequate level of tissue quality and safety.

## 29. RISK MANAGEMENT

Risk management is a systematic process for the assessment, control, communication and review of risks. It can be applied both proactively and retrospectively.

Risk must be identified and assessed and all Risk management procedures must be developed, documented and monitored for relevance within the specific tissue banking practice.

## 30. SAFETY AND FACILITIES

The facility shall establish and maintain policies, processes, and procedures designed to minimize risks to the health and safety of employees, donors, patients, volunteers, and other persons affected within the work environment. Suitable quarters, environment, and equipment shall be available to maintain safe operations. National, provincial, and local regulations and by-laws will apply.

### 30.1 Safety

Policies, processes, and procedures shall identify and address the hazards present in the facility, including biological, chemical, and, where applicable, radiation safety and appropriate intervention to limit exposure and shall include a system for monitoring training and compliance. Biohazardous materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

### 30.2 Facilities

The facility shall be designed to ensure donor, patient, employee, and product safety and shall be suitable for the activities performed.