American Association of Tissue Banks

*S*elf-assessment *T*ool / *A*udit *R*eport (STAR)

Based on AATB *Standards for Tissue Banking*, 12th Edition (2008)

Includes Changes (in blue) from:

- **Approved Updates to Consent-related Standards, with attachments (March 26, 2011)**
- **AATB Bulletin 11-01, 01/04/11 (D3.000, D4.350, K2.210, K2.220)**
- **AATB Accreditation Policies, September 2011**

November 2011

AUDIT CONFIRMATION

Check one

☐ **Internal Audit of Tissue Bank** **Audit Date(s): _____**
☐ **External Audit of Outside Entities** **Audit Date(s): _____**

For External Audits:

Name and address of outside facility audited:

_____
_____
_____

This Audit Confirmation (page i) is to be submitted to AATB as follows:

1. **Internal audit of facility – By January 31 each year.**
2. **External Audit of outside organization(s) – Submit with the completed Accreditation Application only when applying or reapplying for accreditation. One Audit Confirmation (page i) must be submitted for each entity audited.**

ONLY submit the Audit Confirmation (page i); do NOT submit the completed audit form.

Facility Name: _____

Address: _____

_____

_____

_____ _____ _____
Individual Completing the Audit Confirmation Title Telephone

_____ _____
Signature of Person Completing the Audit Confirmation Date

Activities audited: _____

_____

_____

PLEASE MAKE A COPY OF THIS PAGE AND COMPLETE FOR EACH ENTITY AUDITED
Submit to: AATB, 1320 Old Chain Bridge Rd, Ste. 450, McLean, VA 22101

INSTRUCTIONS FOR COMPLETING THE STAR

USES:

This Self-assessment Tool/Audit Report (STAR) was developed by the American Association of Tissue Banks (AATB) and must be used for the following activities. Written confirmation of its completion must be submitted to the AATB as outlined below:

- Performing an internal audit of the facility
- Performing external audits of facilities that perform activities or services for the facility.

INTERNAL AUDIT: As stated in item I.C. of the AATB *Accreditation Policies*, each accredited facility must complete the STAR, annually. If you have a form for internal audits that you believe is comparable to the STAR that you wish to use instead, you may submit a copy of the form to AATB for review. If AATB determines that your form is equivalent, we will notify you that your form may be used instead of the STAR. Only forms that have been approved for use by AATB may be substituted for the STAR. However, you still must submit the Audit Confirmation (page i of the STAR) to document that the audit was performed. The STAR (or your approved audit form) is to be completed and retained on file at the facility to document that the audit was completed.

EXTERNAL AUDIT: The AATB *Standards for Tissue Banking* indicates that before executing a contract, agreement, or other arrangement with an entity to perform any activity, the accredited tissue bank must ensure that the entity will comply with applicable AATB standards, federal regulations, and applicable state or local laws. Thereafter, the accredited tissue bank is responsible for certifying biennially, that the activities or service(s) performed by others have been performed in conformance with the *Standards*, federal regulations, and applicable state or local laws. This must be documented on a form provided by AATB (STAR), or pre-approved by the AATB Accreditation Program Manager. The verification of activities or services for others shall be documented (e.g. a paper audit, on-site audit, on-site inspection, etc.). Regardless of whether the facility performing activities or services for others is accredited by AATB, it is the responsibility of the tissue bank receiving those services/activities to periodically verify that procedures related to the activities/services performed are in compliance with the AATB *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract. The information regarding the systems reviewed shall be provided to AATB inspectors upon request.

If you use a form for external audits that you believe is comparable to the STAR that you wish to use instead, you may submit a copy of the form to AATB for review. If AATB determines that your form is equivalent, we will notify you that your form may be used instead of the STAR. However, you still must submit the Audit Confirmation (page i of the STAR) to document that the audit was performed. Only forms that have been approved for use by AATB may be substituted for the STAR. The STAR (or your approved audit form) is to be completed and retained on file at the facility to document that the audit(s) was completed.

COMPLETING THE FORM:

- Mark the appropriate response "Yes No N/A." If the entire section does not apply, mark the N/A box (☐) at the top of the section.
- Indicate, in each section, your procedure number(s) and SOPM volume number, or where the standard is addressed in other facility documents.
- If desired, you may use other forms in conjunction with the STAR.
- Attach additional pages if necessary.
- Photocopy the STAR and the Audit Confirmation (page i) as needed.

AATB STANDARDS SECTION B
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

N/A ☐

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

A – Autologous; C – Cardiac; V – Vascular; MS – Musculoskeletal; OA – Osteoarticular; S – Skin; SB – Surgical Bone; LD - Living Donor; DM – Dura Mater

B1.100 Purpose, Institutional Identity, and Affiliations (Mission Statement)

Does the contracting facility maintain a mission statement? Yes ☐ No ☐ N/A ☐

B1.200 Governing Body

Does the Bank have a governing Body? Yes ☐ No ☐ N/A ☐

If yes, what type? Board of Trustees _____ Board of Governors _____Board of Directors _____

Who is the designated responsible individual in whom policy-making authority resides?

_____

B1.300 Medical Scientific Support

Is there a mechanism to access medical, technical, and scientific data? Yes ☐ No ☐ N/A ☐

Where do you document decisions resulting from medical, technical, or scientific advice?

_____

B1.400 Satellite Facilities N/A ☐

Do the satellite facilities operate according to your SOPM? Yes ☐ No ☐ N/A ☐

☐ Review audits of your satellite facilities to make sure they are operating according to your SOPM, Standards, federal regulations, applicable state or local laws, and the written agreement/contract (if applicable).

☐ Show the administrative relationships on your bank's organizational chart.

B1.500 Multi-Facility Tissue Banking N/A ☐

Are the responsibilities between the tissue bank and the contracting facility(ies) clearly documented and available for review? Yes ☐ No ☐ N/A ☐

How do you ensure the contracting facility(ies) comply with AATB *Standards*?

_____
_____
_____

Do you process tissue for a tissue bank located outside of the U.S.? Yes ☐ No ☐ N/A ☐

If yes, how do you ensure tissue is properly quarantined and that the bank complies with appropriate government regulations?

_____
_____
_____

B1.510 Written Agreements/Contracts

Does the bank have a written agreement/contract with each organization that performs or for whom they perform donor screening/acceptability services, tissue recovery, processing, or distribution? Yes ☐ No ☐ N/A

Do banks that determine donor suitability develop and maintain policies and procedures that clearly describe donor records deemed relevant to their operations? Yes ☐ No ☐ N/A

Does the contract with the tissue bank include the following:

- Nature of the relationship Yes ☐ No ☐ N/A ☐
- Division of tasks performed Yes ☐ No ☐ N/A ☐
- Division of issues of liability Yes ☐ No ☐ N/A ☐
- Specific responsibilities of each party Yes ☐ No ☐ N/A ☐
- Summary of the protocols and procedures relating to the service provided Yes ☐ No ☐ N/A ☐
- Reference to *AATB Standards as applicable* Yes ☐ No ☐ N/A ☐
- Requirement to have a Medical Director Yes ☐ No ☐ N/A ☐
- Requirement to share information in a timely fashion Yes ÿ No ÿ N/A ÿ

☐ Review the contract(s)

B1.521 Inspections/Audits of Other Facilities

Before performing any activity under contract, agreement, or other arrangement, do you ensure that these tissue banking organizations that perform activities/services for you, comply with AATB *Standards*, federal regulations, and applicable state and/or local laws? Yes ☐ No ☐ N/A ☐

Is a paper audit, on-site audit, and/or inspection conducted of activities performed for you by other tissue banking organizations? Yes ☐ No ☐ N/A ☐

Are audits/inspections of non-AATB-accredited banks performed at least biennially and is documentation maintained? Yes ☐ No ☐ N/A ☐

Are audits/inspections of AATB-accredited banks performed periodically and is documentation maintained? Yes ☐ No ☐ N/A ☐

What do you do if you are lead to believe that the entity performing activities/services for you may no longer be in compliance with AATB *Standards*, federal regulations, applicable state and/or local laws?

_____

_____

Do you terminate the agreement/contract if it is determined that the entity will not comply with requirements? Yes ☐ No ☐ N/A ☐

☐ Review audit schedule and audits/inspections for those entities that provide activities/services to you.

Bl.600 Contracted Laboratory Services **N/A** ☐

Does the tissue bank maintain contracts for those laboratory services used? Yes ☐ No ☐ N/A ☐

Do contracts for laboratory services include the following:

- Name and address of the contracted facility Yes ☐ No ☐ N/A ☐
- Documentation of the inclusive dates of the contract period Yes ☐ No ☐ N/A ☐
- Proof of laboratory licensure and accreditation Yes ☐ No ☐ N/A ☐

Does the facility ensure that the laboratory performing donor infectious disease testing:

- Is registered with FDA as a tissue establishment and lists "testing" as a function Yes ☐ No ☐ N/A ☐
- Uses FDA-licensed/approved or cleared screening tests Yes ☐ No ☐ N/A ☐
- Follows manufacturer's instructions Yes ☐ No ☐ N/A ☐
- Maintains infectious disease test run records for at least ten years Yes ☐ No ☐ N/A ☐

Does the facility ensure and maintain documentation that the laboratory performing microbiology testing relating to determining donor suitability:

- Is registered with FDA as a tissue establishment and lists "processing" as a function Yes ☐ No ☐ N/A ☐
- Follows applicable manufacturer's instructions for these tests Yes ☐ No ☐ N/A ☐
- Retains tissue microbiological identification records for 10 years Yes ☐ No ☐ N/A ☐

Are audits/inspections conducted of laboratories that provide serology testing and recovery culture results? Yes ☐ No ☐ N/A ☐

Are audits/inspections conducted of organizations that provide equipment and instrument sterilization? Yes ☐ No ☐ N/A ☐

How often are audits/inspections performed of laboratories that provide serology testing, recovery culture testing, and equipment/instrument sterilization?

_____

Who is responsible for carrying out the audits/inspections of outside partners/contractors?

_____
(Name and Position of Person)

✔ Randomly select a contract to review for inclusion of the above information.

Contract reviewed _____

B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK

B2.100 Tissue Bank Director

B2.110 Qualifications
B2.120 Tissue Bank Director Responsibilities
B2.121 General
B2.122 Personnel

Is there a current organizational chart delineating the functions of each staff member within the organization? Yes ☐ No ☐ N/A ☐

☐ Review the organizational chart.

Are the job descriptions documented and current? Yes ☐ No ☐ N/A ☐

✔ Randomly select two job descriptions.

Name of Staff _____
Job Description _____
Last review date _____

Name of Staff _____
Job Description _____
Last review date _____

Does the Director attend an AATB meeting or workshop at least once every three years, obtain at least 15 CEUs/CMEs, and is this documented? Yes ☐ No ☐ N/A ☐

B2.123 Implementation and Evaluation of Donor Suitability Assessment Criteria and of all Technical Policies and Procedures

Is the Director or designee responsible for reviewing and approving all technical policies and procedures? Yes ☐ No ☐ N/A ☐

How is the review and approval accomplished?

_____
_____
_____

How does the Director ensure compliance with all applicable federal, state, and/or local laws and/or regulations?

_____
_____
_____

Are standard procedures prepared by another organization utilized by the bank? Yes ☐ No ☐ N/A ☐

How do you verify that these procedures are consistent with, and at least as stringent as, AATB *Standards*?

_____
_____

B2.124 Quality Assurance Program

Is an annual internal audit/review performed and documented to ensure compliance with current SOPs, federal, state, and/or local laws and/or regulations and *AATB Standards?* Yes ☐ No ☐ N/A ☐

Who performs the annual audit/review?

_____

Is the STAR used as the internal audit form? Yes ☐ No ☐ N/A ☐

If no, when was your audit form approved by the AATB? _____

☐ Review the most recent internal audit.
☐ Review the audit schedule.

Date of last audit _____

B2.200 Medical Director **N/A** ☐

B2.210 Qualifications

Does the tissue bank have a Medical Director who is a licensed physician in the United States or abroad? Yes ☐ No ☐ N/A ☐

Medical Director name _____

Is the Medical Director's license current? Yes ☐ No ☐ N/A ☐

Does the Medical Director attend an AATB meeting or workshop at least once every three years, obtain at least 15 CMEs/CEUs and is this documented? Yes ☐ No ☐ N/A ☐

B2.220 Responsibilities
B2.221 Donor Suitability Criteria

Has the Medical Director reviewed and approved the donor suitability criteria? Yes ☐ No ☐ N/A ☐

Does the Medical Director evaluate and determine each donor's acceptability prior to release of tissue? Yes ☐ No ☐ N/A ☐

How does the facility ensure that all SOPs that are medical in nature are reviewed and approved by the Medical Director?

_____
_____
_____

B2.222 Adverse Outcomes

Has the Medical Director established policies and procedures regarding investigating and documenting adverse outcomes? Yes ☐ No ☐ N/A ☐

Are corrective actions documented? Yes ☐ No ☐ N/A ☐

Are final summary reports reviewed and approved by the Medical Director? Yes ☐ No ☐ N/A ☐

B2.223 Notification of Confirmed Positive Test Results

Does the Medical Director notify appropriate parties of confirmed positive infectious disease test results? Yes ☐ No ☐ N/A ☐

How does the Medical Director ensure compliance with applicable federal, state, and local laws and/or regulations when notifying parties of confirmed positive infectious disease tests?

_____
_____
_____

B2.300 Technical Staff **N/A** ☐

B2.310 Qualifications

How do you ensure that staff has the appropriate education, experience, and training to perform assigned tasks?

_____
_____
_____

B2.320 Responsibilities

Are the duties of each staff member described in a written job description? Yes ☐ No ☐ N/A ☐

B2.400 Quality Assurance Program

Does the tissue bank maintain a quality assurance program? Yes ☐ No ☐ N/A ☐

What function(s) is(are) the quality assurance department currently performing?

_____
_____
_____

B2.410 Staff Qualifications

Is an individual, not directly responsible for the performance of operations, responsible for the quality systems review? Yes ☐ No ☐ N/A ☐

To whom does this individual report?

_____
Name Title

What are this person's responsibilities?

_____
_____
_____

B2.420 Staff Responsibilities

Do Quality Assurance Program personnel have responsibility for assuring compliance with SOPM and regulatory requirements? Yes ☐ No ☐ N/A ☐

How do Quality Assurance Program personnel ensure compliance with SOPM and regulatory requirements?

_____
_____
_____

What quality system review process is established to approve or reject donor tissue?

_____
_____
_____

☐ Review quality system review of donor tissue procedure.

AATB STANDARDS SECTION C
RECORDS MANAGEMENT

N/A ☐

C1.000 RECORDS MANAGEMENT

N/A ☐

C1.100 General

Does the donor record management system ensure documentation of all applicable aspects of the tissue banking process? Yes ☐ No ☐ N/A ☐

Is documentation done concurrently with performance of each step? Yes ☐ No ☐ N/A ☐

What action is taken to ensure that donor confidentiality is maintained?

_____
_____
_____

How do you ensure records are complete and accurate and contain all elements listed in standard C1.100?

_____
_____
_____

C1.110 Required Processing Documentation

Are laboratory test results maintained by the tissue bank that determines suitability? Yes ☐ No ☐ N/A ☐

Are all other processing records available to the distributor on site or by facsimile, within the same workday? Yes ☐ No ☐ N/A ☐

C1.120 Electronic Records

Are records maintained electronically? Yes ☐ No ☐ N/A ☐

If yes, how do you ensure data integrity is maintained and information is available?

_____
_____
_____

Can electronic records be printed as a hard copy? Yes ☐ No ☐ N/A ☐

C1.200 Availability for Inspection

Are donor records (including electronic records) readily available for inspection? Yes ☐ No ☐ N/A ☐

C1.300 Retention

What is the record retention policy?

_____
_____
_____

How are archived records stored?

_____
_____

_____

Is this an environment that will preserve the records? Yes ☐ No ☐ N/A ☐

Are they stored according to applicable laws and regulations? Yes ☐ No ☐ N/A ☐

C1.400 Traceability

Is a unique donor identifier assigned? Yes ☐ No ☐ N/A ☐

How does the tissue bank ensure that laboratory specimens (blood samples, procurement cultures, lymph nodes etc.) are identified with the proper identifier?

_____
_____
_____

Is tissue consigned to a non-accredited entity? Yes ☐ No ☐ N/A ☐

If yes, how do you ensure that the non-accredited entity complies with requirements of Section C in the AATB *Standards for Tissue Banking*?

_____
_____
_____

C1.500 Revisions

Does the procedure regarding revisions include the following requirements:

- A single line is drawn through altered text. Yes ☐ No ☐ N/A ☐
- Revisions are initialed and dated by the individual making the revision. Yes ☐ No ☐ N/A ☐
- Additions to completed records are initialed and dated by the person making the addition. Yes ☐ No ☐ N/A ☐

C2.000 CONSTRUCTION OF RECORDS

N/A ☐

Are donor charts assembled in a uniform manner? Yes ☐ No ☐ N/A ☐

Are relevant medical records reviewed for completeness and accuracy before release of tissue? Yes ☐ No ☐ N/A ☐

Are records in English, or if in another language, translated into English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document? Yes ☐ No ☐ N/A ☐

How do you ensure that you do not utilize documentation related to consent/ authorization or donor risk assessment that is obtained by unauthorized parties?

_____
_____
_____

Are authorized parties identified in agreements and are personnel performing these functions qualified, trained, and competent? Yes ☐ No ☐ N/A ☐

☐Review record construction procedures.

Are autologous tissue records maintained in a separate log, or if incorporated into general records, maintained in such a manner that the autologous tissue may not be released for non-autologous use? Yes ☐No ☐ N/A ☐

Do cardiac records meet the general criteria and also include:

- ABO/Rh if available — Yes ☐ No ☐ N/A ☐
- Date/time of asystole — Yes ☐ No ☐ N/A ☐
- Date/time of recovery of heart (time when subjected to cold rinse solution) — Yes ☐ No ☐ N/A ☐
- Date/time subjection of cardiac allograft tissue to disinfection solution — Yes ☐ No ☐ N/A ☐
- Start and stop times when tissue subjected to disinfection solution — Yes ☐ No ☐ N/A ☐
- Date/time when preservation began and when placed in the final container — Yes ☐ No ☐ N/A ☐

Do vascular records meet the general criteria and also include:

- ABO/Rh if available — Yes ☐ No ☐ N/A ☐
- Date/time of asystole — Yes ☐ No ☐ N/A ☐
- Date/time vascular tissues subjected to perfusion solution — Yes ☐ No ☐ N/A ☐
- Date/time vascular tissues placed in transport solution and subjected to wet ice temperatures — Yes ☐ No ☐ N/A ☐
- Date/time of subjection of vascular tissue to disinfection solution — Yes ☐ No ☐ N/A ☐
- Start and stop times when tissue subjected to disinfection solutions — Yes ☐ No ☐ N/A ☐
- Date/time when preservation began and when placed in the final container — Yes ☐ No ☐ N/A ☐

C3.000 DONOR RECORDS TO BE MAINTAINED

N/A ÿ

How do you ensure donor records are maintained according to AATB standards?

_____
_____
_____

C4.000 PROCESSING RECORDS

N/A ÿ

Are tissues processed by another organization? Yes ÿ No ÿ N/A ÿ

If tissues are processed by another agency, how do you ensure that processing and QC records are retained as required?

_____
_____
_____

AATB STANDARDS SECTION D
ACQUISITION OF TISSUE: CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

N/A ☐

D1.000 GENERAL POLICIES FOR TISSUE RECOVERY ORGANIZATIONS

Are the arrangements with the donor referral services documented? Yes ☐ No ☐ N/A ☐

D1.100 Does the facility have a policy regarding monetary compensation? Yes ☐ No ☐ N/A ☐
(Moved from D3.000.)

☐ Review your policy regarding monetary compensation.
Does it comply with the standard? Yes ☐ No ☐ N/A ☐

D2.000 AUTHORIZATION

N/A ☐

D2.100 Authorization Requirements

Does the tissue bank obtain authorization, to acquire tissues and make them available for transplantation, in writing, in accordance with applicable anatomical gift acts or other laws or regulations? Yes ☐ No ☐ N/A ☐

Are appropriate records maintained? Yes ☐ No ☐ N/A ☐

☐ Review authorization procedure. Procedure number _____

D2.200 Conditions

How do you ensure adequate information concerning the donation and recovery of tissue is presented in a language in which the authorizing person is conversant and in terms that are easily understandable by the authorizing person?

_____
_____
_____

How do you ensure that coercion or inaccurate information is not used in any manner to obtain authorization?

_____
_____
_____

☐ Review authorization training procedures to make sure individuals are trained not to use coercion.

D2.300 Signatures and Documentation

D2.310 Document of Gift

When a donor has executed a Document of Gift, is it acted upon only if it meets applicable laws and regulations? Yes ☐ No ☐ N/A ☐

How do you ensure that authorization is adequate regardless of the method used to obtain it?

_____

D2.320 Document of Authorization

When a Document of Authorization is used does it contain the required elements? Yes ☐ No ☐ N/A ☐

D2.330 – Methods of Obtaining Authorization

If authorization is obtained in person, does the authorizing person read and sign the Document of Authorization? Yes ☐ No ☐ N/A ☐

If authorization is obtained by telephone, is the Document of Authorization read to the authorizing person by the person obtaining authorization or, alternatively, is each core element described (see D2.400)? Yes ☐ No ☐ N/A ☐

Is the telephone conversation recorded? Yes ☐ No ☐ N/A ☐

Is a sampling plan used to verify that recordings match the content in the written Document of Authorization? Yes ☐ No ☐ N/A ☐

Is the sampling performed by someone other that the Donation Coordinator or witness? Yes ☐ No ☐ N/A ☐

If the Document of Authorization is provided by fax, is a copy of the Document of Authorization provided to the Authorizing Person? Yes ☐ No ☐ N/A ☐

Does the Authorizing Person return the signed Document of Authorization by fax? Yes ☐ No ☐ N/A ☐

Does the sampling plan verify signatures received by fax and is the verification performed by someone other than the Donation Coordinator or Witness? Yes ☐ No ☐ N/A ☐

If authorization is obtained by electronic transmission, is a copy of the Document of Authorization provided to the Authorizing Person? Yes ☐ No ☐ N/A ☐

Does the Authorizing Person electronically respond (e.g., by email) that he/she has read the Document of Authorization, is authorized to grant authorization, and is granting authorization? Yes ☐ No ☐ N/A ☐

Is the Document of Authorization obtained by electronic transmission verified according to the relevant law on electronic signatures? Yes ☐ No ☐ N/A ☐

Is the Donation Coordinator available to respond to questions from the Authorizing Person? Yes ☐ No ☐ N/A ☐

D2.400 Core Elements for Authorization **N/A** ☐

Are the Core Elements included in the Document of Authorization? Yes ☐ No ☐ N/A ☐

Is the Authorizing Person provided with the information required in Standard D2.400? Yes ☐ No ☐ N/A ☐

If an OPO or other entity (e.g., hospital) has initiated the process of obtaining authorization for a potential organ and tissue donor, does the tissue bank for which the authorization is being obtained request that the OPO or other entity follow the procedure and utilize a Document of Authorization that complies with standard D2.000? Yes ☐ No ☐ N/A ☐

For a donor one month (28 days) of age or less, is adequate consent pursuant to the law obtained for collection of blood from the birth mother? Yes ☐ No ☐ N/A ☐

D2.500 Notification of Gift **N/A** ☐

How do you ensure that an appropriate Document of Gift has been obtained when the gift is authorized by the donor's own Document of Gift?

_____
_____
_____

When law mandates notification when you have a Document of Gift, is notification made according to law? Yes ☐ No ☐ N/A ☐

Is notification documented? Yes ☐ No ☐ N/A ☐

If good faith efforts to notify an appropriate person of the gift are not successful, is the attempt documented? Yes ☐ No ☐ N/A ☐

☐ Review applicable procedure(s) for completeness. Procedure number _____

D2.600 Services to Donor Families

Do you provide services to donor families or referral to a support system? Yes ☐ No ☐ N/A ☐

Are subsequent communications documented, maintained and available? Yes ☐ No ☐ N/A ☐

D3.000 INFORMED CONSENT FOR LIVING DONORS AND CLIENT DEPOSITORS

D3.100 – Requirements

Is informed consent obtained from the living donor or client depositor in accordance with applicable laws and regulations? Yes ☐ No ☐ N/A ☐

Is the informed consent documented in an Informed Consent Record and is the original or a copy maintained in the living donor's or client depositor's record at the tissue bank responsible for recovery or collection, as well as the living donor's record at the tissue bank whose Medical Director is responsible for donor suitability determination? Yes ☐ No ☐ N/A ☐

If an electronic or voice recorded Informed Consent is obtained, is the original recording maintained in reproducible form? Yes ☐ No ☐ N/A ☐

D3.200 – Conditions

How do you ensure that adequate information concerning the recovery or collection of tissue is presented in a language in which the living donor or client depositor is conversant and in terms that are easily understandable?

_____
_____
_____

How do you ensure that neither coercion nor inaccurate information is used in any manner to obtain informed consent and that the potential donor is not under

the influence of anesthesia or any drug that could influence his/her ability to give informed consent?

_____
_____
_____
_____

For autologous tissue, in informed consent to store tissue obtained prior to recovery (or when recovery has already occurred, as soon as practical after recovery) and before use of the tissue? Yes ☐ No ☐ N/A ☐

D3.300 – Signatures and Documentation

Does the Informed Consent Record comply with applicable laws and regulations and contain the items listed in standard D3.300? Yes ☐ No ☐ N/A ☐

D3.310 – Methods of Obtaining Informed Consent

Check the methods you use for obtaining informed consent:
1) _____ In person
2) _____ By telephone
3) _____ By facsimile (fax)
4) _____ Use of electronic transmission.

Review your procedures and forms to ensure that you comply with all requirements listed in standard D3.310 for the methods you use for obtaining informed consent and provide the results of the review.

_____
_____
_____

D3.400 – Core Elements for Informed Consent

Does Informed Consent from a living donor or client depositor contain all core elements listed in standard D3.400? Yes ☐ No ☐ N/A ☐

D4.000 DONOR SUITABILITY

N/A ☐

D4.100 General

Is donor suitability performed according to AATB Standards and your SOPM? Yes ☐ No ☐ N/A ☐

D4.200 Donor Assessment

D4.210 Physical Assessment

Are deceased donors subject to a physical assessment prior to recovery? Yes ☐ No ☐ N/A ☐

Does the physical assessment include evaluation for any evidence of:

- Sexually transmitted diseases -genital ulcerative disease, herpes simplex, syphilis, chancroid (*genital lesions*) Yes ☐ No ☐ N/A ☐
- Physical evidence for risk of or evidence of

syphilis (genital lesion, rash, skin lesion *(non-genital)* Yes ☐ No ☐ N/A ☐

- For male donor: anal intercourse including perianal Condyloma (*insertion trauma, perianal lesions*) Yes ☐ No ☐ N/A ☐
- Needle track marks *(non-medical injection sites) including exam of tattoos which may cover needle tracks)* Yes ☐ No ☐ N/A ☐
- Disseminated lymphadenopathy *(enlarged lymph nodes)* Yes ☐ No ☐ N/A ☐
- Unexplained oral thrush *(white spots in mouth)* Yes ☐ No ☐ N/A ☐
- Blue or purple spots consistent with Kaposi's sarcoma (*blue/purple [gray/black] spots/lesions)* Yes ☐ No ☐ N/A ☐
- Physical evidence of recent tattooing, ear piercing, or body piercing [should be described]) Yes ☐ No ☐ N/A ☐
- Hepatitis Yes ☐ No ☐ N/A ☐
- Jaundice Yes ☐ No ☐ N/A ☐
- Hepatomegaly Yes ☐ No ☐ N/A ☐
- Icterus Yes ☐ No ☐ N/A ☐
- Bacterial infection Yes ☐ No ☐ N/A ☐
- Trauma Yes ☐ No ☐ N/A ☐
- Physical evidence of sepsis Yes ☐ No ☐ N/A ☐
- Large scab consistent with recent smallpox immunization Yes ☐ No ☐ N/A ☐
- Eczema vaccination *(lesion/scab)* Yes ☐ No ☐ N/A ☐
- Generalized vesicular rash, generalized vaccinia (rash) Yes ☐ No ☐ N/A ☐
- Severely necrotic lesion consistent with vaccinial keratitis Yes ☐ No ☐ N/A ☐
- Corneal scarring consistent with vaccinial keratitis Yes ☐ No ☐ N/A ☐

What is the written protocol if any of the above is noted?

_____

_____

☐ Review physical exam procedure. Procedure number _____

D4.211 Physical Examination

For a living donor (LD) except autologous or embryo donation, prior to the donation of tissue, is a physical exam performed by the Medical Director or physician designee or by a physician involved with the individual's medical care or his/her designee? Yes ☐ No ☐ N/A ☐

Is a donor risk assessment interview performed for the LD? Yes ☐ No ☐ N/A ☐

Is the information obtained used to determine donor suitability? Yes ☐ No ☐ N/A ☐

D4.220 Medical, Social and Sexual History Inquiry

Is an inquiry conducted to gain insight into the donor's medical, social, and sexual history? Yes ☐ No ☐ N/A ☐

Is an appropriate, standardized questionnaire used for the inquiry? Yes ☐ No ☐ N/A ☐

Who is eligible to answer medical, social, and sexual inquiries about the donor?

_____

_____

_____

Appendix II:
CRITERIA FOR PREVENTING TRANSMISSION of RCDADs (Relevant Communicable Disease Agents and Diseases)[1] THROUGH TRANSPLANTATION OF HUMAN tissue

Behavior/History Exclusionary Criteria

1) Men who have had sex with another man within the preceding five years;

2) Persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections;

3) Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates in the preceding five years;

4) Persons who have had sex in exchange for money or drugs in the preceding five years;

5) Persons who have had sex in the preceding 12 months with any person described in the 4 items above or with any person who has HIV infection, including a positive test for HIV, hepatitis B infection, or clinically active (symptomatic) hepatitis C[2] infection;

6) Persons who have been exposed within the preceding 12 months to known or suspected HIV, HBV, and/or HCV infected blood through percutaneous inoculation (e.g., needlestick) or through contact with an open wound, non-intact skin, or mucous membrane;

7) Children born to mothers known to be HIV-infected or at risk for HIV infection, who are 18 months of age or less and/or have been breastfed in the preceding 12 months, regardless of the child's (donor's) HIV status;

   NOTE: Children over 18 months of age born to mothers infected with HIV or at risk for infection, who have not been breast fed within the preceding 12 months, and whose HIV antibody test, *Physical Examination*, and review of medical records do not indicate evidence of HIV infection, may be accepted as donors.

8) Persons who have been in juvenile detention, lockup, jails or prisons for more than 72 consecutive hours in the preceding 12 months;

9) Persons with a generic history of hepatitis of an unspecified etiology or a current or past diagnosis of clinical, symptomatic viral hepatitis unless evidence from the time of illness documents that the hepatitis was diagnosed as either hepatitis A or due to cytomegalovirus or Epstein-Barr virus hepatitis. (Note: A verbal history of viral hepatitis occurring before the age of 11 years is acceptable);

10) Persons who have lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months;

11) Persons who had or have been treated for syphilis or gonorrhea during the preceding 12 months. Donors may be acceptable if evidence is presented that the treatment occurred more than 12 months ago and was successful;

12) Persons who within 12 months prior to donation have undergone tattooing, acupuncture, ear or body piercing in which shared instruments are known to have been used;

13) Persons with a diagnosis of any form of Creutzfeldt-Jakob disease (CJD) or known family history (blood relative) of a person with non-iatrogenic CJD;

14) Persons with a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology. Note: tissues from donors with dementia, confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of TSE on microscopic examination of the brain, may be acceptable based on an evaluation of this information by the Medical Director.);

15) Persons who have received injections of human pituitary-derived growth hormone (pit-hGH);

16) Persons who are known to have received transplants of human *Dura Mater*

17) Persons with encephalitis or meningitis of viral or unknown etiology that is active;

18) Persons who have received transfusions of blood or blood products outside of the United States during specific time periods in the following countries:
   a. From 1980 to present: France or the United Kingdom (includes England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands); and/or
   b. After 1977 to present: Central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria)[3] ;

19) Persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:
   a. Spent three months or more cumulatively in the United Kingdom (U.K) from the beginning of 1980 through the end of 1996;
   b. Lived cumulatively for 5 years or more in Europe[4] from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996); and/or
   c. Is a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996;

20) Persons who, within the previous 120 days, have been told by a healthcare professional that they were suspected or known to have had a West Nile Virus (WNV) infection based on symptoms, and/or those who are known to have tested positive for WNV by a NAT assay within this time frame;

21) Persons who are known to have risks associated with xenotransplantation[5] (i.e. receipt of a xenotransplantation product[6] or who has had intimate contact[7] with a *Recipient* of a xenotransplantation product);

22) Persons who have been permanently deferred as a blood donor for unknown reasons or who have a history of positive infectious disease test results for HIV, HBV, or HCV;

23) Persons who, within the past six months, were bitten by an animal suspected to be infected with rabies. Individuals with suspected rabies shall not be accepted as donors under any circumstances. (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

24) Persons who have known or suspected sepsis at the time of death, or at the time of donation in the case of a *Living Donor*;

25) Persons who, since 1977, were born in or have lived in any area of central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, and Nigeria) and persons known to have had sexual contact with any such person[3];

26) Persons who have had recent smallpox vaccination (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact[8] with someone who received the smallpox vaccine;

27) Persons whose cause of death (COD) cannot be determined and there is likelihood of other exclusionary criteria; and

28) Persons who are known to have malaria or be at risk for malaria.

[1]RELEVANT COMMUNICABLE DISEASE AGENT OR DISEASE (RCDAD) – a potentially infectious *Microorganism*, virus, or other disease agent that may pose a risk of transmission to *Recipients* of, or those who come in contact with, tissues. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential donor population; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for donor specimens has been cleared, approved, or *FDA*-licensed, and is available. They can also be those disease agents or diseases that could place potential donors and/or *Recipients* at risk for infection due to accidental or intentional release. RCDADs applicable to all cell and/or tissue donors are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, SARS (when applicable), WNV, vaccinia, and sepsis.

Donors of viable, leukocyte-rich tissues must additionally consider HTLV I/II, and donors of reproductive tissues must generally consider *Chlamydia trachomatis* and *Neisseria gonorrhea*.

[2]CLINICALLY ACTIVE HEPATITIS C - infection with hepatitis C virus when it is symptomatic. This means that: the person demonstrates related symptoms such as jaundice, icterus, fatigue, abdominal pain, loss of appetite, nausea, vomiting, diarrhea, low grade fever, headache, joint pain, and/or "flu-like symptoms" **AND**, HCV infection is suspected or has been diagnosed or anti-HCV (EIA) testing is positive. Also, knowledge of a recent/current positive test for HCV NAT would qualify as a clinically active HCV infection.

[3]Tissue Banks using an HIV test that has been approved by FDA to include a donor screening clam for detection of HIV Group O antibodies are not required to screen for this risk history.

[4]European countries to be used for deferral of donors based on geographic risk of Bovine Spongiform Encephalopathy (BSE): Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, and Yugoslavia.

[5]XENOTRANSPLANTATION – any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) live cells, tissues, or organs from a nonhuman animal source; or (2) human body fluids, cells, Tissues, or organs that have had ex vivo contact with live nonhuman animal cells, Tissues, or organs.

[6]XENOTRANSPLANTATION PRODUCT – live cells, tissues, or organs used in xenotransplantation. Biological products, drugs, or medical devices sourced from nonliving cells, tissues, or organs from nonhuman animals, including but not limited to porcine insulin and porcine heart valves, are not considered xenotransplantation products.

[7]XENOTRANSPLANTATION INTIMATE CONTACT: An ‘‘intimate contact of a xenotransplantation product recipient’’ is a person who has engaged in activities that could result in the intimate exchange of body fluids with a xenotransplantation product recipient. Examples of intimate contacts include, but are not limited to, sexual partners, household members who share razors or toothbrushes, and health care workers or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures. Mere sharing of domicile or casual contact, such as hugging or kissing without the exchange of saliva, would not be interpreted as intimate contact.

[8]CLOSE CONTACT: SMALLPOX - Physical contact with the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an un-bandaged vaccination site.

Sources:

U.S. Department of Health and Human Services, Food and Drug Administration, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule (69 FR 29785, May 25, 2004) http://www.fda.gov/cber/rules/suitdonor.pdf

U.S. Department of Health and Human Services, Food and Drug Administration, Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) dated August 8, 2007. http://www.fda.gov/cber/gdlns/tissdonor.pdf

U.S. Department of Health and Human Services, Food and Drug Administration, Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria dated June 2000. http://www.fda.gov/cber/gdlns/malaria.pdf

D4.230 Relevant Medical Records Review

Prior to donation, is a preliminary review of readily available medical information conducted by a trained individual? Yes ☐ No ☐ N/A ☐

Is the reason for the deferral of a donor documented? Yes ☐ No ☐ N/A ☐

Prior to the release of tissue for transplantation, does the Medical Director or licensed physician designee determine donor suitability? Yes ☐ No ☐ N/A ☐

If the donor's death did not occur in a hospital or no third party records are available that can be used to establish a likely cause of death, and if no autopsy was performed, is a certified copy of the death certificate included in the donor record? Yes ☐ No ☐ N/A ☐

D4.240 Donor Autopsy Report

How does the Medical Director or licensed physician document review of the autopsy report or summary of findings?

_____
_____
_____

If the autopsy report is not available for the donor's record, is the cause of death and other pertinent autopsy findings documented in the donor record? Yes ☐ No ☐ N/A ☐

Is it noted and taken into consideration if an autopsy was not performed due to risk of infectious disease or if special precautions were taken during the autopsy that would suggest risk of exposure to a communicable disease? Yes ☐ No ☐ N/A ☐

D4.300 Disease Screening

D4.310 Infections

What procedure(s) is established to prevent the tissue bank from releasing tissue to the processing phase that exhibits any of the following:

- Septicemia
- Viral disease (e.g. HIV, viral hepatitis, WNV, SARS, rabies, etc.)
- Human transmissible spongiform encephalopathies
- Untreated syphilis
- Clinically active tuberculosis
- Leprosy (Hansen's disease)
- Systematic mycosis
- Risk factors for Relevant Communicable Diseases or Disease Agents (RCDADs) as specified in Appendix II

_____
_____
_____

If dura mater is recovered, does a qualified pathologist perform an examination of the donor's brain as specified in this standard? Yes ☐ No ☐ N/A ☐

☐ Review release procedure. Procedure number _____

D4.320 Miscellaneous Adverse Conditions

What is the protocol for the release of tissues from a donor if the donor has a history of:

- Autoimmune disease
- Ingestion of, or exposure to, toxic substances

_____
_____
_____

☐ Review the written protocol. Does it adhere to AATB standard D4.320? Yes ☐ No ☐ N/A ☐

D4.330 Risk Factors

How do you ensure tissue from high risk donors is not distributed?

_____
_____
_____

D4.340 Malignancies

Is tissue from a donor with a current or prior diagnosis of malignancy accepted? Yes ☐ No ☐ N/A ☐

What is the written protocol for the release of tissues from a donor with a current or prior diagnosis of malignancy?

_____
_____
_____

☐ Review protocol for malignancy.

Does it adhere to AATB standard D4.340? Yes ☐ No ☐ N/A ☐

D4.350 Blood Tests
D4.351 Specimens

Is testing of donor blood specimens performed? Yes ☐ No ☐ N/A ☐

What is the procedure for the collection of donor blood (specifically the allowed time frame for collection)?

Deceased Donors:_____
_____
_____

Living Donors:_____
_____
_____

☐ Review collection of donor blood procedure. Procedure number _____

D4.352 Plasma Dilution

Does the tissue bank maintain and use a plasma dilution procedure/ algorithm for assistance in the evaluation of donor blood when blood loss is known or suspected to have occurred? Yes ☐ No ☐ N/A ☐

Is the plasma dilution procedure/algorithm performed according to AATB Standards and the facility's SOPM? Yes ☐ No ☐ N/A ☐

Does the SOPM address additional circumstances when plasma dilution may have occurred (e.g. large volumes of transfusions/ infusions administered in the absence of blood loss)? Yes ☐ No ☐ N/A ☐

D4.353 Infections Disease Testing

What is the policy for the final disposition of donor tissue when the donor is repeatedly reactive on a required screening test?

_____
_____
_____

Who is responsible?

_____

How do you ensure that FDA-licensed approved or cleared donor screening tests are used and, when applicable, tests are used that are labeled for cadaveric specimens?

_____
_____
_____

How do you ensure manufacturer's instructions are followed?

_____
_____
_____

How do you ensure that new tests are implemented when AATB and/or FDA issues notification to implement such tests?

_____
_____
_____

D4.354 Required Infectious Disease Tests

Are required infectious disease tests performed? Yes ☐ No ☐ N/A ☐

Reference Donor Chart Checklist, item 2g (attached to the back of the STAR).

D4.355 Interpretation of Infectious Disease Test Results

How does the facility ensure the disposition of allogeneic tissue is based upon a complete interpretation of all infectious disease test results?

_____
_____
_____

D4.356 Notification of Donors with Positive Blood Infectious Disease Test Results

Does the Medical Director maintain a policy/procedure for notifying the appropriate parties if an infectious disease test is positive? Yes ☐ No ☐ N/A ☐

☐ Review procedure/policy for the following:

- Reference to the state/local regulation (Next of kin or physician notification)
- Notification to the Health Department
- Notification to exposed personnel
- Testing of exposed personnel
- Documentation requirements

D4.357 Archived Samples

Does the tissue bank have a policy to archive donor serum, plasma, and/or hematopoietic tissue samples even if the donor is determined to be unsuitable? Yes ☐ No ☐ N/A ☐

If donor samples are archived, what is the retention policy?

_____
_____
_____

Are appropriate brain tissue specimens from each dura mater donor archived under appropriate storage conditions for the appropriate duration? Yes ☐ No ☐ N/A ☐

☐ Review archive storage area, log books, etc.

D4.400 Age Criteria

What are your bank's current age criteria for the following:

- Fascia Lata _____
- Ribs _____
- Cartilage _____
- Achilles Tendon _____
- Patellar Tendon _____
- Large bones (Femur, Tibia, Fibula, Pelvis, Humerus, Ulna, Radius, and Vertebral Bodies) _____
- Mandible _____
- OA (Osteoarticular) _____

How does the Medical Director and/or Medical Advisory Committee determine age criteria?

_____
_____
_____

☐ Review written age criteria policy(ies).

D4.500 Information Sharing

If the donor is unsuitable, does the facility share information with all establishments who are known to have recovered or received tissue from the donor and is this documented? Yes ☐ No ☐ N/A ☐

Is record sharing performed timely? Yes ☐ No ☐ N/A ☐

Are records that could affect donor suitability sent without delay to banks that will determine donor suitability and according to written agreements? Yes ☐ No ☐ N/A ☐

Is pre-processing culture information shared with all tissue banks to whom tissue from shared donors was sent, unless declined according to a written agreement? Yes ☐ No ☐ N/A ☐

Are their written procedures for receiving, investigating, evaluating, and documenting donor information and how information will be shared? Yes ☐ No ☐ N/A ☐

D5.000 RECOVERY AND COLLECTION POLICES AND PROCEDURES

N/A ☐

D5.000 Recovery Donor Policies and Procedures

How do you ensure that recovery policies and procedures are established in accordance with AATB *Standards*?

_____
_____
_____

Does the tissue bank specify the site where the tissue is to be obtained and the general recovery environment? Yes ☐ No ☐ N/A

D5.100 Verification Procedures
D5.110 Confirmation

Prior to recovery, how does staff ensure that Authorization for donation has been obtained and documented in a Document of Gift (for deceased donor) or that Informed Consent for donation has been obtained and documented for a Living Donor?

_____
_____
_____

☐ Review the procedure. Procedure number _____

D5.120 Donor Identity

How does recovery/collection staff ensure that donor identity verification complies with standard D5.120?

_____
_____
_____

D5.200 Donor Identification Number

How does the facility ensure that a unique donor identification number is assigned to each donor?

_____
_____
_____

D5.300 Tissue Recovery – General

Are recovery personnel adequately trained to retrieve tissue within specified time limits? Yes ☐ No ☐ N/A ☐

Does the SOPM indicate time limits for the postmortem recovery of tissue? Yes ☐ No ☐ N/A ☐

Is recovery from one donor the exclusive activity taking place at one time at the recovery site? Yes ☐ No ☐ N/A ☐

How do you ensure that other activities (e.g. embalming, autopsy, another tissue recovery) do not occur simultaneously in the same room as the recovery?

_____
_____
_____

What is the policy if recovery is delayed for deceased donors?

_____
_____
_____

D5.400 Time Limits for Tissue Recovery

How do you ensure staff adheres to appropriate time limits?

_____
_____
_____

D5.500 Recovery Environment

Is all tissue recovered in an aseptic/clean fashion? Yes ☐ No ☐ N/A ☐

Is the recovery site evaluated for suitability using pre-established criteria designed to control contamination and cross-contamination and is this evaluation documented? Yes ☐ No ☐ N/A ☐

☐ Review sterile technique for donor tissue recovery procedure.

D5.501 Recovery Site Suitability

Are there recovery site suitability parameters that address the control of:

- Size/shape Yes ☐ No ☐ N/A ☐
- Lighting Yes ☐ No ☐ N/A ☐
- Plumbing and drainage for the intended use Yes ☐ No ☐ N/A ☐
- Physical state of the facility Yes ☐ No ☐ N/A ☐
- Ventilation Yes ☐ No ☐ N/A ☐
- Cleanliness of room and furniture surfaces Yes ☐ No ☐ N/A ☐
- Pests Yes ☐ No ☐ N/A ☐
- Traffic Yes ☐ No ☐ N/A ☐
- Location Yes ☐ No ☐ N/A ☐
- Other activities occurring simultaneously Yes ☐ No ☐ N/A ☐
- Source of contamination Yes ☐ No ☐ N/A ☐
- Ability to dispose of biohazardous waste and handle contaminated equipment Yes ☐ No ☐ N/A ☐

D5.510 Recovery Cleansing and Preparation

Is aseptic technique followed? Yes ☐ No ☐ N/A ☐

Is the recovery site evaluated to identify potential sources of contamination? (See AATB Guidance Document 2) Yes ☐ No ☐ N/A ☐

How do you ensure that cleansing and disinfection activities performed by tissue banking personnel are documented?

_____
_____
_____

Do technicians follow aseptic technique (refer to AORN)? Yes ☐ No ☐ N/A ☐

D5.520 Recovery Technique

Does the sterile technique procedure include the following guidelines:

- Surgical scrub of hands and forearms Yes ☐ No ☐ N/A ☐
- A head cover and mask worn at the time of scrub Yes ☐ No ☐ N/A ☐
- Eye shields worn at the time of scrub Yes ☐ No ☐ N/A ☐
- A sterile gown and gloves are put on after the scrub Yes ☐ No ☐ N/A ☐

Are specific tissue recovery operations used to control contamination and cross-contamination (e.g. sequencing of the tissue recovery, use of well-defined zone recovery techniques, and isolation draping in the presence of trauma? Yes ☐ No ☐ N/A ☐

D5.521 Cultures Obtained at Recovery (MS, OA, S, SB)

If recovery cultures are obtained, is the technique used to obtain cultures appropriate for the tissue type and performed according to written procedures? Yes ☐ No ☐ N/A ☐

D5.600 Recovery Records

Are appropriate details of tissue recovery documented in recovery records? (Reference Donor Chart Checklist at the end of the STAR). Yes ☐ No ☐ N/A ☐

Are microbiological cultures taken and documented as per K2.210? Yes ☐ No ☐ N/A ☐

D5.700 Post-Recovery Packaging

Is each individual tissue wrapped using a standard method? Yes ☐ No ☐ N/A ☐

Is the receptacle immediately labeled with the donor ID number and type of tissue enclosed. Yes ☐ No ☐ N/A ☐

What information is recorded on the individual tissue labels?

_____
_____
_____

☐ Review packaging procedure. Procedure number _____

D5.800 Transportation of Tissue to Processing Center

Has the contracted facility validated the packaging and transport conditions (temperatures) of frozen tissue shipped to the tissue bank? Yes ☐ No ☐ N/A ☐

☐ Review validation procedure. Procedure number _____

☐ Review validation data for tissue transportation.

If shipping container validation has not been performed, what temperature monitoring does the bank do?

_____
_____

_____

Does the shipping container include the following information:

- DONATED HUMAN TISSUE Yes ☐ No ☐ N/A ☐
- Name/address of the recovery agency Yes ☐ No ☐ N/A ☐
- Name/address of processing facility (if different) Yes ☐ No ☐ N/A ☐
  (in accordance with federal, state, and/pr local laws and/or regulations.)
- Quarantine status Yes ☐ No ☐ N/A ☐

D5.810 Time Limit for Receipt by Processing Center

How do you ensure that cardiac and vascular tissue is received at the processing center within sufficient time following recovery to allow for the start of disinfection, within the established cold ischemic time limit?

_____
_____
_____

D5.900 Post-Recovery Reconstruction of Cadaveric Donor

Does the facility maintain a procedure for donor reconstruction that is consistent with funeral home guidelines and/or medical examiner or pathologist requests? Yes ☐ No ☐ N/A ☐

☐ Review post-recovery operations and documentation. Procedure number _____
Reference Donor Chart Checklist at the back of the STAR for additional assessment

D6.000 Reagents and General Supplies

How does the facility ensure that all instruments, solutions, and supplies used to recover human tissue used for transplantation are sterile (unless otherwise indicated)?

_____
_____
_____

How does the facility ensure all non-disposable surgical instruments and parts of equipment that come into contact with tissues during cell and/or tissue recovery are properly cleaned, disinfected, and sterilized between donor recoveries?

_____
_____
_____

Are reagents stored in accordance with manufacturer's instructions? Yes ☐ No ☐ N/A ☐

STANDARDS SECTION E
PROCESSING, PRESERVATION,
QUARANTINE, AND STORAGE

N/A ☐

Please Note: This section is intended for processing facilities, although some of the sections are applicable to procurement activities and quality related functions.

E1.000 PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE – GENERAL

N/A ☐

Has the director established processing and preservation methods that ensure that all tissue will be processed, preserved, quarantined, and stored in accordance with *AATB Standards*? Yes ☐ No ☐ N/A ☐

E1.010 Receipt of Tissue at Processing Center

Is cardiac and/or vascular tissue received at your facility? Yes ☐ No ☐ N/A ☐

How does the facility document that the temperature range of 1 to 10°C has been maintained during the transport of cardiac and/or vascular tissue?

_____
_____
_____

Is there documentation of:

1) The transport device condition Yes ☐ No ☐ N/A ☐
2) Date and time of movement into storage at the processing facility Yes ☐ No ☐ N/A ☐
3) Personnel involved Yes ☐ No ☐ N/A ☐

E1.020 Processing Environment

Are all tissues processed in an environment designed to control air quality and prevent microbiological contamination? Yes ☐ No ☐ N/A ☐

☐ Review processing procedure. Procedure number _____

E1.030 Processing Methods

Is tissue processed by methods known to be validated to prevent contamination and cross-contamination? Yes ☐ No ☐ N/A ☐

E1.032 Documentation of Tissue Condition

Is a detailed physical description of the cardiac and/or vascular allograft recorded in the permanent donor processing record? Yes ☐ No ☐ N/A ☐

Are abnormalities and/or imperfections documented? Yes ☐ No ☐ N/A ☐

E1.033 Temperature Limits

Does the facility process cardiac, vascular, or skin tissue? Yes ☐ No ☐ N/A ☐

How does the facility ensure appropriate temperatures are maintained?

_____

_____

_____

E1.034 Prevention of Matrix Deterioration

Is cardiac, vascular tissue, and/or skin tissue kept moist during processing? Yes ☐ No ☐ N/A ☐

E1.035 Additives

Are additives used in freezing specified in the SOPM? Yes ☐ No ☐ N/A ☐

Is information regarding additives made available to the Implanting/transplanting physician, upon request? Yes ☐ No ☐ N/A ☐

E1.036 – Time Limit for Dissection

Does the total ischemic time not exceed 48 hours for cardiac or vascular tissue? Yes ☐ No ☐ N/A ☐

E1.040 Sterilization/Disinfection of Tissue

If tissues are sterilized or disinfected, do procedures comply with *AATB Standards*? Yes ☐ No ☐ N/A ☐

Does the discard list for cardiac and vascular tissue include fungi (yeasts, molds), Clostridium, and Streptococcus pyogenes (group A strep)? Yes ☐ No ☐ N/A ☐

For skin, does the discard list include staphylococcus aureus, Streptococcus pyogenes (group A strep), Enterococcus species, gram-negative organisms, Clostridium, fungi (yeast, molds)? Yes ☐ No ☐ N/A ☐

Is the list based upon the category type of tissue and the method by which the tissue was processed? Yes ☐ No ☐ N/A ☐

E1.041 Disinfection of Tissue

Are there procedures for time-specific validated incubation and regimen (Disinfection time)? Yes ☐ No ☐ N/A ☐

E1.042 Non-Terminal Irradiation

Is musculoskeletal tissue exposed to non-terminal irradiation? Yes ☐ No ☐ N/A ☐

Is a dose selected to reduce or eliminate bioburden? Yes ☐ No ☐ N/A ☐

Is the selected dose justified and are claims supported by data? Yes ☐ No ☐ N/A ☐

Is appropriate information regarding irradiation indicated on the

container label or package insert? Yes ☐ No ☐ N/A ☐

E1.043 Terminal Tissue Sterilization by Irradiation

Is the irradiation source and dosimetry identified in the processing record? Yes ☐ No ☐ N/A ☐

Is a completed certificate of irradiation in the processing record? Yes ☐ No ☐ N/A ☐

Is the sterilization dose validated? Yes ☐ No ☐ N/A ☐

How do you ensure that the sterilization dose is capable of achieving the sterility assurance level?

_____

_____

_____

☐ Review the sterilization procedures. Procedure number(s) _____

E1.044 Terminal Sterilization by Other Methods

How does the facility ensure sterilization if methods other than irradiation are used?

_____

_____

_____

If ethylene oxide sterilization is utilized, how do you ensure that elimination of residual ethylene oxide and/or its breakdown products?

_____

_____

_____

☐ Review the sterilization procedures. Procedure number(s) _____

E1.045 Disinfection by Chemical Agents

Does the facility disinfect tissue using chemical agents? Yes ☐ No ☐ N/A ☐

How do you ensure appropriate chemical agents are used?

_____

_____

_____

E1.046 Other Disinfection Agents

If used, have procedures for processing with heat, ultraviolet radiation, or exposure to antibiotics been documented and validated? Yes ☐ No ☐ N/A ☐

E1.050 Tissue Evaluation

Does the facility have a standardized evaluation and classification system? Yes ☐ No ☐ N/A ☐

If imperfect allografts are dispensed, is notification documented? Yes ☐ No ☐ N/A ☐

E1.060 Tissue Preservation/Cryopreservation

Do techniques and procedures affecting the preservation or cryopreservation of tissue conform to *AATB Standards* E1.061-E1.069, where applicable? Yes ☐ No ☐ N/A ☐

E1.100 Tissue Identification

Are tissues given a unique identifier that relates clearly to the donor's unique identification? Yes ☐ No ☐ N/A ☐

E1.200 Pooling

How does the facility ensure that pooling is prohibited?

_____
_____
_____

E1.210 Tissue Cross-Contamination

How does the facility ensure procedures are followed for the prevention of infectious disease contamination or cross-contamination during processing?

_____
_____
_____

☐ Review the procedure. Procedure number _____

E1.300 Reagents and Supplies – General

Is an incoming inspection performed on reagents and supplies? Yes ☐ No ☐ N/A ☐

Are reagents and supplies of an appropriate use? Yes ☐ No ☐ N/A ☐

Are reagents and supplies retained and used in a manner that complies with *AATB Standards* E1.300-E1.320? Yes ☐ No ☐ N/A ☐

El.310 Stock Rotation
E1.311 Storage

Is a just-in-time (JIT) philosophy or first in, first out (FIFO) philosophy used to support an adequate stock rotation? JIT ☐ FIFO ☐

Are reagents stored according to manufacturer's instructions? Yes ☐ No ☐ N/A ☐

E1.320 Non-Disposable Supplies

How do you ensure non-disposable supplies are properly cleaned, disinfected, or sterilized between donors?

_____
_____
_____

E1.400 Tracing of In-Process Tissue

How do you ensure traceability of the tissue?

_____
_____
_____

E1.500 Time Limits for Processing and Preservation Phases

Are time limits and/or other process-control end points established for each phase of processing and preservation? Yes ☐ No ☐ N/A ☐

E1.600 Tolerance Limits of Processed Tissue

Does the bank have written procedures identifying specifications, tolerance limits, and a method of final evaluation for processed tissues? Yes ☐ No ☐ N/A ☐

E1.610 Specimen Sizing

Is cardiac and vascular tissue inspected, evaluated, and sized by Internal valve annulus diameter, and recorded in millimeters? Yes ☐ No ☐ N/A

Is the length of the vascular segment recorded in centimeters? Yes ÿ No ÿ N/A

E1.620 Calcium Residuals: Demineralized Bone

Are representative samples of each lot tested for residual calcium and does residual calcium not exceed 8%? Yes ☐ No ☐ N/A ☐

E1.700 In Process Controls

Are in-process controls applied according to SOPM? Yes ☐ No ☐ N/A ☐

How do you ensure tissue has the identity, characteristics, and quality intended?

_____
_____
_____

E1.800 Processing and Preservation Records

Does the bank document the processing and preservation of tissue by recording the elements required in *AATB* standard E1.800? Yes ☐ No ☐ N/A ☐

E1.900 In-House Laboratory Testing

Does the bank perform laboratory tests where the results are used to determine acceptability of tissue for transplantation? Yes ☐ No ☐ N/A ☐

How is staff performing the tests certified competent to perform the tests?

_____
_____
_____

E1.910 Laboratory Records

Do records of in-house laboratory testing include required information? Yes ☐ No ☐ N/A ☐

E1.920 Laboratory Controls

Are there adequate provisions for monitoring reliability, accuracy, precision, and performance of test procedures and instruments? Yes ☐ No ☐ N/A ☐

E2.000 CONTAINERS

N/A ☐

E2.000 Containers
E2.100 Physical Properties

Are containers handled and stored in a manner that complies with *AATB Standards* E2.100-E2.500? Yes ☐ No ☐ N/A ☐

☐ Review container procedure. Procedure number _____

E2.200 Receipt of New Shipments

How does the facility ensure containers are appropriately stored in quarantine?

_____
_____
_____

E2.300 Storage

Are unused containers appropriately handled and stored? Yes ☐ No ☐ N/A ☐

E2.400 Integrity and Sterility

How does the facility ensure sterile containers are not contaminated during handling?

_____
_____
_____

E2.500 Visual Inspection

What happens to containers not meeting specifications?

_____
_____
_____

E3.000 QUARANTINING

N/A ☐

E3.100 Quarantine Areas

Are quarantine areas physically separated and clearly labeled to distinguish quarantine tissue from tissues not suitable for transplantation, and from tissue available for distribution? Yes ☐ No ☐ N/A ☐

☐ Review quarantine procedure. Procedure number _____

E3.200 Situations Requiring Quarantine

Is tissue quarantined until all criteria for donor suitability are satisfied? Yes ☐ No ☐ N/A ☐

Is there a specific area designated for quarantine? Yes ☐ No ☐ N/A ☐

E3.300 Labeling Quarantined Tissue

Is tissue processed or shipped prior to determination of donor suitability? Yes ☐ No ☐ N/A ☐

If yes, is tissue kept under quarantine and accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation? Yes ☐ No ☐ N/A ☐

E3.400 Quarantine Records

Are freezer logbooks maintained indicating:

- Log in dates Yes ☐ No ☐ N/A ☐
- Donor identification number Yes ☐ No ☐ N/A ☐
- Donor tissues Yes ☐ No ☐ N/A ☐
- Log out dates Yes ☐ No ☐ N/A ☐
- Personnel involved in transfer of donor tissues Yes ☐ No ☐ N/A ☐

☐ Review quarantine record procedure. Procedure number _____

☐ Review quarantine records. Freezer number and logbook audited _____

E4.000 STORAGE

N/A ☐

E4.100 Storage Temperatures

Does the tissue bank maintain a freezer temperature monitoring system? Yes ☐ No ☐ N/A ☐

E4.110 Refrigerated Tissue

Are there written procedures for storing refrigerated musculoskeletal and skin tissue to ensure optimum quality? Yes ☐ No ☐ N/A ☐

E4.120 Frozen and Cryopreserved Tissue

E4.130 Lyophilized/Dehydrated Tissue

How does the facility ensure tissue is stored at appropriate temperatures?

_____

_____

_____

E4.140 Monitoring Storage Temperatures

Is a temperature monitoring system used? Yes ☐ No ☐ N/A ☐

How is staff alerted when temperatures have strayed outside acceptable limits?

_____

_____

_____

Who is responsible for responding to a freezer alert?

_____

Does the tissue bank have a procedure to review freezer temperature data on a regular basis? Yes ☐ No ☐ N/A ☐

Is the review documented? Yes ☐ No ☐ N/A ☐

☐ Review freezer temperature monitoring procedure. Procedure number _____

E.4.141 Storage Conditions for Commonly Transplanted Human Tissue

Storage Conditions for Commonly Transplanted Human Tissue		
Human Tissue	**Storage Conditions**	**Temperature (^{0}C)***
Cardiac and Vascular	Frozen, cryopreserved	-100^{o}C or colder
Dura	Lyophilized	Ambient***
Musculoskeletal	Refrigerated	1-10^{o}C
	Frozen, cryopreserved and non-cryopreserved (temporary storage less than 6 months)	-20^{o}C to –40^{o}C **
	Frozen, cryopreserved and non-cryopreserved (long term storage)	-40^{o}C or colder
	Lyophilized	Ambient***
Reproductive	Frozen, cryopreserved	LN_2(Liquid or Vapor Phase)
Skin	Refrigerated	1-10^{o}C
	Frozen, cryopreserved	-40^{o}C or colder
	Lyophilized	Ambient***
Soft tissue (e.g. parathyroid)	Frozen, cryopreserved	Not Established

* Warmest target temperature unless noted to be a range.
** Frozen musculoskeletal: -20^{o}C to – 40^{o}C for storage 6 months or less.
*** Ambient temperature monitoring not required for lyophilized tissue.

E4.150 Emergency Transfers

In the event that a freezer is unable to maintain an adequate temperature range, what alternative solutions are available?

_____
_____
_____

Who is responsible for directing the necessary actions for an emergency transfer?

_____

How did the facility confirm the emergency storage space is adequate?

_____
_____
_____

☐ Review emergency transfer procedure. Procedure number _____

E4.200 Storage Devices

Does the facility ensure food and/or liquids for human consumption are not stored in devices used to store tissue, reagents, media, refrigerants, etc.? Yes ☐ No ☐ N/A ☐

E4.300 Expiration Date/Storage Period

How does the facility ensure the maximum storage period for tissue is appropriate and according to AATB Standards?

_____
_____
_____

E4.310 Refrigerated Time

Is the refrigerated time within AATB standards? Yes ☐ No ☐ N/A ☐

E4.320 Frozen and Cryopreserved Cells and Tissue

Is MS or OA stored longer than five years?	Yes ☐ No ☐ N/A ☐
If yes, was the process validated?	Yes ☐ No ☐ N/A ☐

E4.330 Lyophilized/Dehydrated Tissue

Is MS tissue lyophilized or dehydrated?	Yes ☐ No ☐ N/A ☐
If yes, is it stored for not more than five years unless a longer expiration date has been validated?	Yes ☐ No ☐ N/A ☐

E4.400 Segregation of Cells and Tissue

How does the facility segregate autologous tissue that tests positive for infectious diseases?

_____
_____
_____

AATB STANDARDS SECTION F
RELEASE AND TRANSFER OF TISSUE

N/A ☐

F1.000 TISSUE RELEASE – GENERAL REVIEW REQUIREMENTS

N/A ☐

Is all necessary information completed and compiled in a standardized format prior to final review? Yes ☐ No ☐ N/A ☐

Are appropriate signatures obtained for release? Yes ☐ No ☐ N/A ☐

F1.100 Donor Suitability Review

Is all donor suitability information reviewed by the appropriate individual? Yes ☐ No ☐ N/A ☐

Does the donor suitability review include all required elements listed in the *Standards*? Yes ☐ No ☐ N/A ☐

Is the recovery site suitability reviewed by the appropriate individual? Yes ☐ No ☐ N/A ☐

How does a contracting recovery facility ensure that the information above is sent to the tissue bank? (internal checklist, internal medical records review...)

_____
_____
_____

Who is responsible for the final review of the donor chart before it is sent to the tissue bank?

_____

How is the review documented?

_____
_____
_____

F1.200 Technical Review

Is a proper review performed prior to release of tissue for transplantation? Yes ☐ No ☐ N/A ☐

F1.300 Quality Assurance/Quality Control Review

Does the responsible person release tissue for transplantation only with a documented disposition/release statement? Yes ☐ No ☐ N/A ☐

F1.310 Review of On-Site Processing Records

Is processing performed on site? Yes ☐ No ☐ N/A ☐

If yes, is there written documentation that all quality assurance and control measures were performed and acceptable? Yes ☐ No ☐ N/A ☐

F2.000 OTHER RELEASE

N/A ☐

Does the facility have pre-established release criteria for tissue to be released based on tissue utility? Yes ☐ No ☐ N/A ☐

If tissue is released based on tissue utility, are the following documented:

- Donor suitability and tissue processing information available at the time of release Yes ☐ No ☐ N/A ☐
- Assurance that all donor suitability requirements in F1.100 are met except a review of the autopsy report (if applicable) and pending culture results Yes ☐ No ☐ N/A ☐
- Medical Director or licensed physician designee review of all relevant information present Yes ☐ No ☐ N/A ☐
- Approval of release by the Medical Director/licensed physician designee Yes ☐ No ☐ N/A ☐
- Statement issued to end-user physician indicating what information required by the SOPM and/or *Standards*
  - is available Yes ☐ No ☐ N/A ☐
  - is not available (and when information will be available) Yes ☐ No ☐ N/A ☐
- When relevant final test results are available, documentation that this information is forwarded promptly to the end-use physician Yes ☐ No ☐ N/A ☐
- Statement from end-user physician indicating his/her understanding that tissue is being released using available information Yes ☐ No ☐ N/A ☐
- Documentation of release based on tissue utility in donor record Yes ☐ No ☐ N/A ☐

☐ Review utility release procedure. Procedure number _____

F3.000 TISSUE FAILING REVIEW PROCESS – GENERAL REQUIREMENTS

N/A ☐

Does the facility have a procedure for quarantining tissue failing any portion of the review process? Yes ☐ No ☐ N/A ☐

How does the facility ensure that quarantined tissue is not released?

_____
_____
_____

☐ Review the quarantine procedure. Procedure number _____

F3.100 Unsuitable Donors

Does the bank or contracting facility maintain a discard procedure for the disposition of unsuitable tissue? Yes ☐ No ☐ N/A ☐

Is unsuitability information communicated timely to the tissue bank that recovers tissue? Yes ☐ No ☐ N/A ☐

Is tissue from unsuitable donors made available for nonclinical purposes? Yes ☐ No ☐ N/A ☐

If this tissue is made available for nonclinical purposes, is it labeled "For Nonclinical Use Only" accompanied by a biohazard legend? Yes ☐ No ☐ N/A ☐

☐ Review the discard procedure. Procedure number _____

F3.200 Technical or Quality Assurance Assessments

Is there documentation of tissue unsuitable for release? Yes ☐ No ☐ N/A ☐

F4.000 TISSUE RELEASE – GENERAL

N/A ☐

F4.100 Release to Distribution Inventory

Is appropriate release documentation completed prior to transfer of tissue from quarantine? Yes ☐ No ☐ N/A ☐

F4.200 Transfer to Other Inventory Locations

If tissue is transferred, is the disposition documented? Yes ☐ No ☐ N/A ☐

AATB STANDARDS SECTION G
LABELING

N/A ☐

G1.000 LABELS AND LABELING

N/A ☐

G1.100 Nomenclature

Does the bank have incorporated in its SOPM, procedures that designate the nomenclature and units of measurement used to describe tissue and the processing the tissue received? Yes ☐ No ☐ N/A ☐

G1.200 Label List

Are preprinted or computer-generated labels used? Yes ☐ No ☐ N/A ☐

If yes, is a list and example of the labels maintained including the start and discontinuance dates? Yes ☐ No ☐ N/A ☐

☐ Review the list and examples of labels.

G1.300 Labeling Integrity

How does the tissue bank ensure labels are clear, legible, and indelible?

_____
_____
_____

G1.400 Claims

How does the facility ensure all labeling claims are accurate, substantiated, and not misleading?

_____
_____
_____

G2.000 LABELING PROCESS

N/A ☐

G2.100 General Requirements

Are SOPs for labeling followed? Yes ☐ No ☐ N/A ☐

Is each labeling phase documented? Yes ☐ No ☐ N/A ☐

☐ Review the labeling procedure. Procedure number _____

G2.200 Re-Labeling

Does the facility have a re-labeling procedure? Yes ☐ No ☐ N/A ☐

Are re-labeling events documented? Yes ☐ No ☐ N/A ☐

G2.300 Controls – General

Are there labeling control procedures? Yes ☐ No ☐ N/A ☐

Do the labeling control procedures include a review of labels to ensure accuracy? Yes ☐ No ☐ N/A ☐

G2.310 Label Inspection

How does the facility ensure labels meet appropriate written specifications?

_____
_____
_____

G2.320 Label Storage

Does the bank clearly identify the storage area for labels? Yes ☐ No ☐ N/A ☐

G2.330 Labeling Process Controls – Obsolete Labels

Are there procedures for retrieving obsolete and/or outdated labels and labeling materials? Yes ☐ No ☐ N/A ☐

How does the facility ensure the Master Label List and SOPM get updated when labels are deleted/changed?

_____
_____
_____

G2.340 Tissue and Container Visual Inspection

Prior to labeling a unit of processed tissue, is the container thoroughly inspected for acceptability? Yes ☐ No ☐ N/A ☐

G3.000 LABELING INFORMATION

N/A ☐

G3.110 Design

Are labels designed to facilitate their use? Yes ☐ No ☐ N/A ☐

G3.120 Label Content and G3.210 Package Insert Content
(See Attachments 1 and 2.)

Do container labels and package inserts conform to applicable requirements of G3.120 and G3.210? Yes ☐ No ☐ N/A ☐

G3.130 Additional Labeling Requirements

Does the facility label autologous tissue? Yes ☐ No ☐ N/A ☐
Does labeling comply with AATB *Standards*? Yes ☐ No ☐ N/A ☐

☐ Review the labeling procedure. Procedure number _____

G3.210 Summary of Records

Is tissue accompanied by appropriate summary of records? Yes ☐ No ☐ N/A ☐

Does summary of records content include:

- Statement that tissue was prepared from a suitable donor Yes ☐ No ☐ N/A ☐
- Results of relevant communicable disease testing performed Yes ☐ No ☐ N/A ☐
- Statement that communicable disease testing was performed by a registered/certified lab Yes ☐ No ☐ N/A ☐
- Name and address of establishment that determined donor suitability Yes ☐ No ☐ N/A ☐

G3.220 Package Insert Content

Do package inserts contain appropriate and complete information (Items 1 – 21 in *Standards and/or 1 – 10 for C,V tissue*)? Yes ☐ No ☐ N/A ☐

Are instructions detailed and clear enough to allow operating room personnel of average skill to follow and complete the procedure successfully? Yes ☐ No ☐ N/A ☐

G3.310 Domestic Shipments

Does the transport package label contain the information required by this standard? Yes ☐ No ☐ N/A ☐

G3.320 – International Shipments

Do labels for international shipments contain all of the information required for domestic shipments? Yes ☐ No ☐ N/A ☐

AATB STANDARDS SECTION H
DISTRIBUTION AND DISPENSING

N/A ☐

H1.000 DISTRIBUTION AND DISPENSING

N/A ☐

Are there SOPs for:

- Receipt of tissue orders — Yes ☐ No ☐ N/A ☐
- Unit selection — Yes ☐ No ☐ N/A ☐
- Final container and/or package inspection — Yes ☐ No ☐ N/A ☐
- Shipping and transportation of tissue for transplantation — Yes ☐ No ☐ N/A ☐

H1.010 Solution

Are any specially required solutions (not readily available in an operating room) needed to complete the cardiac and/or vascular allograft operative preparation? Yes ☐ No ☐ N/A ☐

If yes, are the specially required solutions made available to the utilizing facility? Yes ☐ No ☐ N/A ☐

H1.100 Tissue Distribution and Dispensing Restrictions

Is provision of tissue for transplantation restricted to entities outlined in standard H1.100 (hospitals, free-standing medical facilities, tissue banks, tissue dispensing services, and end-users (e.g. physicians, dentists, podiatrists or other medical professionals)? Yes ☐ No ☐ N/A ☐

H1.200 Transfer of Tissue to Other Banks/Dispensing Services

Does the facility obtain tissue from another tissue bank? Yes ☐ No ☐ N/A ☐

If yes, are all accompanying original labeling materials or other enclosures forwarded with the tissue? Yes ☐ No ☐ N/A ☐

H1.300 Requests for Donor Status and Tissue Processing Information

How does the facility ensure appropriate information is made available to the transplanting physician, upon request?

_____
_____
_____

H1.400 Distribution Records

Are distribution records maintained? Yes ☐ No ☐ N/A ☐

How does the facility ensure tissue can be traced from donor to a consignee or end-user, and from a consignee or end-user back to the donor?

_____
_____
_____

☐ Review records for completeness.

H1.410 Responsibility

Have recipient follow-up data collection protocols been established? Yes ☐ No ☐ N/A ☐

H2.000 TISSUE FOR RESEARCH – GENERAL POLICIES AND PROCEDURES

N/A ☐

If tissue is used for research, how is the donor consent for research verified and documented?

_____
_____
_____

How is donor tissue for research identified when it is shipped to the designated recipient?

_____
_____
_____

H2.100 Written Requests

Are all requests for human tissue intended for research use submitted in writing? Yes ☐ No ☐ N/A ☐

H2.200 Review and Approval

Are tissue requests for research approved by the Director, or Medical Director, or their designee Yes ☐ No ☐ N/A ☐

Is approval based on legal, ethical, and technical considerations that are defined in the SOPM? Yes ☐ No ☐ N/A ☐

H3.000 PACKAGING AND SHIPPING

N/A ☐

How does the facility ensure specifically required solutions needed to prepare allograft skin tissue are made available to the utilizing facility?

_____
_____
_____

H3.100 Integrity

How does the facility ensure packaging maintains tissue integrity and prevents contamination?

_____
_____
_____

H3.200 Tissue Storage Environment

Are defined environmental conditions maintained during transit? Yes ☐ No ☐ N/A ☐

H3.300 Validation and Expiration of Transport Container

Was the transport container validated? Yes ☐ No ☐ N/A ☐
Was the validation documented? Yes ☐ No ☐ N/A ☐

H3.400 Quality Control

How does the facility ensure QC monitoring is performed according to SOPM?

_____
_____
_____

H3.410 Residual Levels in Packaging

Is ethylene oxide used to sterilize processing or packaging components that come in contact with the allograft? Yes ☐ No ☐ N/A ☐

If yes, how are residues evaluated? _____
_____
_____

H3.500 Final Inspection

Are packages inspected to ensure:

Containers are intact Yes ☐ No ☐ N/A ☐
Labels are accurate Yes ☐ No ☐ N/A ☐
Insert is present Yes ☐ No ☐ N/A ☐
Package is appropriate? Yes ☐ No ☐ N/A ☐
DONATED HUMAN TISSUE indicated on the label? Yes ☐ No ☐ N/A ☐

☐ Review the final inspection procedure. Procedure number _____

H3.600 Transportation

How is the mode of transportation selected?

_____
_____
_____

H4.000 RETURN OF TISSUE

N/A ☐

Does the facility have a policy regarding the return of tissue? Yes ☐ No ☐ N/A ☐
Are returns permitted? Yes ☐ No ☐ N/A ☐

If yes, how does the facility ensure proper documentation is maintained on returned tissue?

_____
_____
_____

H4.100 Temperature Records

Is documentation maintained that cardiac, vascular, and osteoarticular tissue is continuously kept at the required storage temperatures? Yes ☐ No ☐ N/A ☐

How do you ensure frozen skin that has been thawed is not returned to inventory?

_____
_____
_____

H5.000 RECALLS—GENERAL

N/A ☐

Does the bank have specific SOPs for the initiation and performance of recalls? Yes ☐ No ☐ N/A ☐

☐ Review the recall procedure. Procedure number _____

Is AATB notified of recalls within 15 days? Yes ☐ No ☐ N/A ☐

H5.100 Circumstances That May Require Recall

How do you ensure tissue is recalled if it was released to distributable inventory or shipped to a consignee and subsequently determined to be unsuitable for transplantation?

_____
_____
_____

H5.200 Notification Responsibilities

How does the bank notify all appropriate entities that received tissue, that the tissue has been recalled?

_____
_____
_____

☐ Review the recall procedures. Procedure numbers _____

H5.300 Handling of Tissue

How does the facility segregate tissue that has been recalled?

_____
_____
_____

H5.400 Recalls of Transplanted Tissue

If recalled tissue has been transplanted or used for research,
is it treated as a potential adverse outcome investigation? Yes ☐ No ☐ N/A ☐

H5.500 Recall Records

Do records pertaining to recall of tissue contain
the appropriate information as listed in standard H5.500? Yes ☐ No ☐ N/A ☐

How do you ensure all information relating to the recall of tissue is completely documented?

_____
_____
_____

☐ Review records for completeness.

Are records pertaining to the recall of tissue retained for at least 10
years beyond the date of distribution, the date of transplantation (if known),

disposition, or expiration of the tissue, whichever is latest? Yes ☐ No ☐ N/A ☐

N/A ☐

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

N/A ☐

J1.100 Purpose and Design

Is there a documented system governing the format for and control over policies/procedures? Yes ☐ No ☐ N/A ☐

☐ Review document system procedure.

J1.200 Contents

Are the facility's SOPM contents complete? (See J1.200 list of SOPM contents). Yes ☐ No ☐ N/A ☐

☐ Review the SOPM for completeness.

J1.300 Implementation

Does the tissue bank have a standard method for handling deviations from written protocol? Yes ☐ No ☐ N/A ☐

J1.400 Modifications

When procedures are modified, are modifications approved by the Director or Medical Director? Yes ☐ No ☐ N/A ☐

Prior to implementing new procedures, is training provided to staff? Yes ☐ No ☐ N/A ☐

Is the nature and date of the procedure change identified on the cover sheet or other associated document? Yes ☐ No ☐ N/A ☐

J1.500 References

How does the facility ensure that copies of publications cited in support of policies or procedures are maintained at the tissue bank?

_____
_____
_____

J1.600 Annual Review

Is an annual review of policies and procedures performed and documented by appropriate individuals? Yes ☐ No ☐ N/A ☐

Who performs the review?

_____
_____

☐ Review SOPs for last review date. _____
(Last review date)

J1.700 Staff Access and Review

Are pertinent and current procedures/policies available to applicable employees at all times? Yes ☐ No ☐ N/A ☐

Where are the designated locations for these policies and procedures?

_____
_____
_____

How are employees updated/trained on changes to procedures?

_____
_____
_____

J1.800 Inspections

Is the SOPM made available for inspection upon request by the AATB or authorized regulatory agencies? Yes ☐ No ☐ N/A ☐

J1.900 Archives

Is there a master list or equivalent control system identifying the current revision status of documents in order to preclude the use of obsolete documents? Yes ☐ No ☐ N/A ☐

Are obsolete procedures archived for 16 years after discontinuation? Yes ☐ No ☐ N/A ☐

Do the archived procedures indicate the dates that each procedure was in use? Yes ☐ No ☐ N/A ☐

☐ Review the archive system.

✔ Randomly review two archived procedures

Procedure reviewed _____ Procedure reviewed _____

J2.000 TECHNICAL AND QUALITY ASSURANCE STAFF – TRAINING/CONTINUING EDUCATION

N/A ☐

J2.100 Training

Does the tissue bank maintain and administer a new employee orientation program? Yes ☐ No ☐ N/A ☐

Is there a training program to train technical and QA Staff regarding applicable federal, state, and/or local law, *AATB Standards*, and internal procedures?

_____
_____
_____

Does training for technical and QA staff include:

SOPM	Yes ☐	No ☐	N/A ☐
Technical training	Yes ☐	No ☐	N/A ☐
QA	Yes ☐	No ☐	N/A ☐
Computer?	Yes ☐	No ☐	N/A ☐

Review the attendance list of the last technical staff training session.

_____

☐ Review employee records for evidence of continuing education and competency testing.

J2.200 Competency

Is the technical staff required to demonstrate specific levels of competency? Yes ☐ No ☐ N/A ☐

How do staff demonstrate competency?

_____
_____
_____

J2.300 Continuing Education

What continuing education is offered to staff?

_____
_____
_____

J2.400 Training Records

✔ Randomly select two training files for review of the following contents:

☐ Training checklist
☐ Description of functions employee is authorized and trained to perform
☐ Documentation of training to applicable SOPs
☐ Annual review of policies and procedures
☐ Annual attendance for hazardous materials training / safety training (where applicable)
☐ Any continuing education records

Name of Staff _____
Position _____
Date of Hire _____

Name of Staff _____
Position _____
Date of Hire _____

J3.000 SAFETY PRACTICES

N/A ☐

J3.100 Work Environment

Are safety procedures included in the SOPM or in a separate safety manual, which is referenced in the SOPM? Yes ☐ No ☐ N/A ☐

J3.200 Procedures

Does the safety program include the following:

- Instructions for contacting emergency personnel Yes ☐ No ☐ N/A ☐
- Evacuation routes and procedures in the event of fire or natural disaster Yes ☐ No ☐ N/A ☐
- Procedures for the management of worker injury Yes ☐ No ☐ N/A ☐
- Incident report procedures (record of medical care received, management notification, and actions to prevent recurrence.) Yes ☐ No ☐ N/A ☐
- Universal Precaution training Yes ☐ No ☐ N/A ☐
- Maintenance of MSDS (Material Safety Data Sheets) Yes ☐ No ☐ N/A ☐
- Storage, handling, and utilization of hazardous materials Yes ☐ No ☐ N/A ☐
- Cleaning biohazard us spills Yes ☐ No ☐ N/A ☐

J3.300 Hazardous Materials Training

Is the training program designed to inform employees about chemical, biological, and radioactive hazards of the workplace as well as the use of personal protection devices? Yes ☐ No ☐ N/A ☐

J3.400 Universal Precautions

Are universal precautions implemented and enforced? Yes ☐ No ☐ N/A ☐

J3.500 Immunization

Is the Hepatitis B vaccination offered to those employees whose job related responsibilities involve potential exposure to blood-borne pathogens? Yes ☐ No ☐ N/A ☐

What is the protocol if an employee is exposed to Hepatitis B?

_____
_____
_____

J3.600 Hazardous Waste Disposal

What is the standard protocol for disposal of hazardous waste?

_____
_____
_____

How do you ensure hazardous waste is disposed of in accordance with applicable federal, state, and local regulations in a manner to minimize environmental impact and exposure of personnel?

_____
_____
_____

J3.700 Personnel

J3.710 Attire

Is adequate attire provided to personnel to minimize spread of transmissible pathogens? Yes ☐ No ☐ N/A ☐

J3.720 Infections

How does the facility ensure staff, with serious infectious conditions (open lesion or apparent illness) that may affect the safety of tissue, are excluded from recovery, processing, preservation, or packaging of tissue until the condition is resolved?

_____
_____
_____

J4.000 FACILITIES

N/A ☐

J4.100 General

Is the facility (physical plant) arranged to meet operational needs? Yes ☐ No ☐ N/A ☐

Are the premises:

Well maintained	Yes ☐	No ☐	N/A ☐
Clean	Yes ☐	No ☐	N/A ☐

Is there adequate:

Plumbing	Yes ☐	No ☐	N/A ☐
Drainage	Yes ☐	No ☐	N/A ☐
Lighting	Yes ☐	No ☐	N/A ☐
Ventilation	Yes ☐	No ☐	N/A ☐
Space	Yes ☐	No ☐	N/A ☐

How do you evaluate the specific suitability parameters for the recovery site?

_____
_____
_____

J4.200 Designated Space

Are critical procedures listed below performed in designated areas?

Processing	Yes ☐	No ☐	N/A ☐
Quarantine storage	Yes ☐	No ☐	N/A ☐
Labeling	Yes ☐	No ☐	N/A ☐
Storage of distributable inventory	Yes ☐	No ☐	N/A ☐
Quality assurance/control functions	Yes ☐	No ☐	N/A ☐
Receipt and storage of containers	Yes ☐	No ☐	N/A ☐
Container labels	Yes ☐	No ☐	N/A ☐
Supplies and reagents	Yes ☐	No ☐	N/A ☐
Storage of medical waste	Yes ☐	No ☐	N/A ☐
Irradiation and other sterilization procedures	Yes ☐	No ☐	N/A ☐
Final product inspection and distribution	Yes ☐	No ☐	N/A ☐
Record storage	Yes ☐	No ☐	N/A ☐

J4.210 Routine Cleaning

Does the facility perform recovery, processing, preservation or other activities where there is potential for cross-contamination or exposure to blood-borne pathogens? Yes ☐ No ☐ N/A ☐

Is routine, scheduled, documented cleaning performed? Yes ☐ No ☐ N/A ☐

J4.300 Environmental Monitoring

Have environmental monitoring procedures been implemented? Yes ☐ No ☐ N/A ☐

How are the environmental monitoring activities documented and trended?

_____
_____
_____ _____

What is the classification of the rooms used for recovery, processing, and/or preservation? (airborne particulate cleanliness class)

_____
_____
_____

For recovery sites, are there pre-established parameters designed to prevent contamination and cross-contamination? Yes ☐ No ☐ N/A ☐

Please Note: The following questions are focused at a contamination control program. If a contamination control program is not instituted, proceed to section J5.000 – Equipment. **N/A ☐**

What methods are used for sampling? (particulate air sampling: non-viable vs. viable, surface cultures, RODAC touch plates)

_____
_____
_____

Is there a protocol for investigation and/or corrective action at pre-determined alert and action levels?

_____
_____
_____

☐ Review environmental monitoring program.

J4.400 Security

Is adequate security provided? Yes ☐ No ☐ N/A ☐

J5.000 EQUIPMENT

N/A ☐

J5.100 Selection

How does the facility ensure that equipment is appropriately sized, designed, and located to facilitate use, cleaning and maintenance?

_____
_____
_____

J5.200 Operation

Is equipment operated according to manufacturer's recommendations? Yes ☐ No ☐ N/A ☐

J5.300 Qualification and Maintenance

What routine maintenance/inspection is performed on the recovery instruments?

_____
_____
_____

Are equipment maintenance files maintained? Yes ☐ No ☐ N/A ☐

Are these files subject to a QA audit/review? Yes ☐ No ☐ N/A ☐

J5.310 Requalification/Recalibration

Following repairs or system upgrades, is equipment requalified and/or recalibrated? Yes ☐ No ☐ N/A ☐

J5.400 Decontamination/Sterilization

Is equipment for sterilizing materials used in tissue recovery, processing, or packaging designed, qualified, maintained, and utilized to ensure adequate function? Yes ☐ No ☐ N/A ☐

How does the facility ensure equipment functions as intended?

_____
_____
_____

Do you recover and/or process dura mater, vertebral bodies, and/or ocular tissue? Yes ☐ No ☐ N/A ☐

If yes, are instruments used to recover and/or process this tissue removed or destroyed if involved in tissue from a donor known or suspected of having a prion-associated disease? Yes ☐ No ☐ N/A

J5.500 Storage Unit Identification

Is each unit used for storage of tissue identified to facilitate monitoring of temperature and location of in-process quarantine and distribution inventory? Yes ☐ No ☐ N/A ☐

AATB STANDARDS SECTION K
QUALITY ASSURANCE

N/A ☐

K1.000 QUALITY ASSURANCE PROGRAM

N/A ☐

Dose the bank maintain a Quality Assurance (QA) program? Yes ☐ No ☐ N/A ☐

K1.100 Basic Elements
Are the following elements included in the QA Program, where appropriate?

1) Quality Control functions
   a) **Environmental monitoring** (J4.300) Yes ☐ No ☐ N/A ☐
   b) **Equipment and facility inspections** - Performance and documentation in maintenance records/logs of periodic equipment and facility inspections (J5.300 Qualification and Maintenance) Yes ☐ No ☐ N/A ☐
   c) **Supply and reagent review** - Performing acceptability determinations of supplies and reagents (E1.300 Supplies and Reagents) Yes ☐ No ☐ N/A ☐
   d) **Equipment monitoring** - review records for maintenance within specified tolerance limits) (J5.300 Qualification and Maintenance Yes ☐ No ☐ N/A ☐
   e) **In-process control** - inspection and monitoring (C1.100 – Records Management, General, E1.800- Processing and Preservation Records) Yes ☐ No ☐ N/A ☐
   f) Monitoring laboratory performance, if applicable Yes ☐ No ☐ N/A ☐
2) **Validation** (shipping container validation) Yes ☐ No ☐ N/A ☐
   (D5.800 Transportation of Tissue to Processing Center) Yes ☐ No ☐ N/A ☐
3) **Corrective action administration**, (K4.000 Investigation) Yes ☐ No ☐ N/A ☐
4) **QA review** - donor screening, recovery, and processing records (F1.100 Donor Suitability Review) Yes ☐ No ☐ N/A ☐
5) **Audit performance** (K5.500 Audits) Yes ☐ No ☐ N/A ☐
6) **Error, accident, complaint, adverse outcome, and recall administration** - documentation, and review (K4.000 Investigations) Yes ☐ No ☐ N/A ☐
7) **Labeling controls** - all brochures, pamphlets, and promotional materials (C1.000 Records Management) Yes ☐ No ☐ N/A ☐
8) **Documentation maintenance** - master SOPM, for those authorized to perform or review tasks, records of names, signatures, initials, or identification codes and inclusive dates of employment**,** master list of labels, reports and conclusions of process validation and equipment qualification studies, records of supply and reagent acceptance, and archived documents (K1.100) Yes ☐ No ☐ N/A ☐
9) **Training** – evaluation of training of personnel and, where possible, the competency of personnel (J2.100 Training, K5.000 Audits) Yes ☐ No ☐ N/A ☐
10) **Information Sharing** – process for sharing information with other Tissue banks that have recovered and/or received Tissues from the same donor Yes □ No □ N/A □

K1.200 Qualification, Verification, and Validation Requirements

Are protocols developed, implemented, and documented for the qualification, verification, and validation of significant components? Yes ☐ No ☐ N/A ☐

Who determines which elements will be qualified, verified, or validated?

_____

K1.210 Validation of Shipping Containers

Are qualification studies performed for cryopreserved cardiac and vascular tissue transportation devices and temporary storage methods to ensure required temperatures are maintained? Yes ☐ No ☐ N/A ☐

K1.220 Validation Procedures - Packaging and Freezing Protocols

Are packaging and freezing protocols validated? Yes ☐ No ☐ N/A ☐

K2.000 QUALITY CONTROL PROGRAM

N/A ☐

Is there a quality control program? Yes ☐ No ☐ N/A ☐

Are the appropriate QC procedures defined? Yes ☐ No ☐ N/A ☐

K2.100 Proficiency Testing

Is appropriate proficiency testing performed? Yes ☐ No ☐ N/A ☐

What happens if there is poor performance on proficiency testing?

_____
_____
_____

K2.200 Microbiological Tissue Cultures

K2.210 Pre-Sterilization/Pre-Disinfection Cultures

Except for skin, has the tissue bank established appropriate pre-sterilization/ pre-disinfection culture methods and sampling strategies to represent all tissues received from a particular donor? Yes ☐ No ☐ N/A ☐

Are the pre-sterilization/pre-disinfection culture results documented in the donor's record? Yes ☐ No ☐ N/A ☐

Does the Medical Director or physician designee review the pre-sterilization/ pre-disinfection culture results prior to release of tissue for transplantation? Yes ☐ No ☐ N/A ☐

(MS, OA, SB) How do you ensure MS, OA, SB tissues with pre-sterilization/ pre-disinfection cultures positive for Clostridium, Streptococcus pyogenes (group A strep) or any other microorganisms determined by the processor to be virulent or difficult to eliminate, are discarded unless treated with a disinfection process validated to eliminate the infectivity of such organisms?

_____

_____

_____

Are other tissues from the same donor that were recovered under conditions that could result in cross-contamination discarded unless they will be treated with a disinfection or sterilization process that has been validated to eliminate the infectivity of such organisms? Yes ☐ No ☐ N/A ☐

For skin, are preprocessing skin cultures from representative anatomic areas obtained prior to exposure of tissue to antibiotic-containing processing solutions? Yes ☐ No ☐ N/A ☐

For skin, are individual anatomic areas yielding cultures positive for microorganisms that are pathogenic highly virulent discarded unless the tissue is disinfected with a validated process? Yes ☐ No ☐ N/A ☐

Does the Medical Director or designee review culture results prior to releasing tissue for transplantation? Yes ☐ No ☐ N/A ☐

Is skin recovery performed as a separate zone from other tissue types? Yes ☐ No ☐ N/A ☐

☐ Review the culturing procedure. Procedure number _____

K2.220 Final/Pre-Packaging

Do all tissue to be released for human transplantation have representative microbiological cultures obtained (includes testing to detect bacteria and fungi)? Yes ☐ No ☐ N/A ☐

Are results documented in the donor record unless dosimetric release has occurred by a validated process according to E1.044? Yes ☐ No ☐ N/A ☐

Are variances in culture results reviewed and approved by the Medical Director or designee? Yes ☐ No ☐ N/A ☐

Except as described for skin, are allografts contained within the processing batch not released if post-processing final sterility test results show organism contamination unless re-worked with an established program validated to eliminate the organism? Yes ☐ No ☐ N/A ☐

Is skin not used for transplantation that has any one of the organisms listed in K2.220 (S) indicated at final culture? Yes ☐ No ☐ N/A ☐

K2.300 Testing for Residues

Are representative cardiac and vascular tissue samples tested to evaluate the concentration of residuals of disinfectants and cryoprotectants (if applicable) initially and after any change in processing involving the components? Yes ☐ No ☐ N/A ☐

K2.400 Other Quality Control Procedures

K2.410 Lyophilized/Dehydrated Tissue

Is one representative sample for each type of tissue dried, or duplicate cortical bone samples from each drier run tested, for residual moisture? Yes ☐ No ☐ N/A ☐

K2.420 Annual Calibrations

Are mechanical storage devices calibrated annually? Yes ☐ No ☐ N/A ☐

K3.000 MICROBIOLOGIC TESTING

N/A ☐

Is the entity performing cultures of tissue for transplantation CLIA-certified? Yes ☐ No ☐ N/A ☐

K3.100 Transport Medium

Does the transport medium maintain the viability of aerobic and anaerobic, bacterial and fungal organisms? Yes ☐ No ☐ N/A ☐

K3.200 Selection of Growth Medium

How does the facility ensure that the growth medium provides optimal conditions to support the growth of aerobic and anaerobic, bacterial and fungal organisms?

_____
_____
_____

K3.210 Quality Control of Growth Medium

Are NCCLS standards followed for quality assurance testing of culture media? Yes ☐ No ☐ N/A ☐

Does the facility prepare its own growth medium? Yes ☐ No ☐ N/A ☐

If yes, are appropriate QC checks performed and documented on each batch of media prepared? Yes ☐ No ☐ N/A ☐

K3.300 Microbiologic Subcultures

Is the organism identified for any positive microbiologic culture to the genus and, where appropriate, to the species level? Yes ☐ No ☐ N/A ☐

K4.000 INVESTIGATIONS

N/A ☐

Does the tissue bank maintain a corrective action procedure? Yes ☐ No ☐ N/A ☐

What circumstances require corrective action?

_____
_____
_____

Who is responsible for the final review of completed corrective action(s)?

_____

☐ Review corrective action procedure. Procedure number _____

K4.100 Errors and Accidents

How are internal nonconformances reported?

_____
_____
_____

Who is responsible for the investigation into reported nonconformances?

_____

Who is responsible for the final review of reported nonconformances?

_____

K4.200 Complaints

Does the tissue bank maintain a customer complaint system Yes ☐ No ☐ N/A ☐

How are customer complaints documented?

_____
_____
_____

☐ Review customer complaint system and files.

K4.300 Adverse Outcomes

Are all reported or suspected adverse outcomes that are potentially related, directly or indirectly, to an allograft investigated thoroughly and expeditiously? Yes ☐ No ☐ N/A ☐

K4.310 Notifications

In accordance with applicable federal, state, and local regulations, are confirmed cases of transmissible disease in a recipient reported in writing in a timely fashion to public health authorities, organ procurement organizations, and appropriate tissue banks? Yes ☐ No ☐ N/A ☐

How do you ensure the reporting to appropriate individuals/entities of confirmed cases of transmissible disease?

_____
_____

K5.000 AUDITS

Reference K5.000 Audits

Are there policies and procedures (P & P) regarding the scope and frequency of internal and external audits? Yes ☐ No ☐ N/A ☐

Cite P&P#_____

How do you ensure that these P&Ps are followed?

_____
_____
_____

Does the QA program review donor information for completeness before review by the Medical Director? Yes ☐ No ☐ N/A ☐

☐ Review the donor information evaluation procedures.

K6.000 COMPUTER/DATA PROCESSING CONTROLS

N/A ☐

K6.100 Authorized Access

How does the facility ensure general access to computer systems is limited to authorized personnel?

_____
_____
_____

How does the facility ensure changes in master production and control records or other records, are instituted only by authorized personnel?

_____
_____
_____

K6.200 Error Reduction

Is automated data processing used for decision making in processing? Yes ☐ No ☐ N/A ☐

If yes, are there adequate procedures implemented to prevent inaccurate input or output and programming errors? Yes ☐ No ☐ N/A ☐

K6.300 Backup Files

Are backup files maintained? Yes ☐ No ☐ N/A ☐

K6.400 Security

How does the facility ensure the safety of back up data?

_____
_____
_____

AATB ACCREDITATION POLICIES

AATB Accreditation Policies

1. How does the bank ensure compliance with AATB Accreditation Policies?

_____
_____
_____

2. Does the tissue bank ensure that AATB is notified of the following reportable events, within the required number of days:

Contrary events (e.g., warning letters, recall notices, deviation reports, changes in licensure, etc.) Yes ☐ No ☐ N/A ☐

Major operational changes (e.g., move, change in Director, Medical Director, QA Director, scope of operations, facilities, name, dissolution of the tissue bank, etc.). Yes ☐ No ☐ N/A ☐

3. Does the tissue bank ensure that AATB is notified when the bank moves or adds locations? Yes ÿ No ÿ N/A ÿ

4. How does the bank ensure that reported events contain the required information?

_____
_____
_____

5. Does the bank provide a copy of any 483s (or equivalent document) received with corrective action within two weeks of submitting the response to FDA (or equivalent organization)? Yes ☐ No ☐ N/A ☐

AATB STANDARDS SECTION L
TISSUE DISPENSING SERVICES

N/A ☐

L1.000 TISSUE DISPENSING SERVICES – GENERAL

N/A ☐

Is the facility a tissue dispensing service? Yes ☐ No ☐ N/A ☐
(Medical, dental, hospital, physician office that receives, stores, and provides tissue directly to an end-user for immediate transplantation.)

How does the facility ensure the safety and traceability of tissue from receipt through clinical use, transfer, or destruction?
_____
_____
_____

L1.100 Director

Are activities supervised by a physician, dentist, podiatrist, or other qualified medical professional? Yes ☐ No ☐ N/A ☐

L2.000 STORAGE

N/A ☐

L2.100– Storage - General

How does the facility ensure tissue is stored in conformance with distributing bank guidelines?
_____
_____
_____

L2.200 – Equipment

Are refrigerators maintained, calibrated, and monitored? Yes ☐ No ☐ N/A ☐

☐ Review QC procedures for refrigerator maintenance, calibration, and monitoring.

✔ Randomly select maintenance records for a refrigerator.
Is the information complete? Yes ☐ No ☐ N/A ☐
Is the maintenance schedule maintained? Yes ☐ No ☐ N/A ☐

Maintenance log reviewed: _____

☐ Procedure numbers _____

L2.300 – Labeling

How does the facility ensure tissue is not relabeled and existing labels are not altered?
_____
_____
_____

L3.000 RELEASE

N/A ☐

L3.100 – Release - Dispensing

Is tissue only dispensed only with an order from a physician or authorized health professional? Yes ☐ No ☐ N/A ☐

How does the facility ensure the source tissue bank's written procedures and directions have been followed regarding transport and preparation for transplantation?

_____
_____
_____

L3.200 – Release to Another Tissue Dispensing Service or Tissue Distribution Intermediary

How do you ensure all appropriate documentation is forwarded with the tissue and appropriate records are maintained?

_____
_____
_____

☐ Review the release procedure. Procedure number _____

L3.300 Tissue Disposal

How does the facility ensure tissue is disposed of in such a manner as to minimize hazards to staff and/or the environment?

_____
_____
_____

Is documentation of notification of the final disposition of tissue recorded? Yes ☐ No ☐ N/A ☐

Is there a written policy for the discard of autologous tissue? Yes ☐ No ☐ N/A ☐

Does the director, in consultation with the patient-donor's physician approve the discard of autologous tissue? Yes ☐ No ☐ N/A ☐

☐ Review the tissue disposal procedures. Procedure numbers _____

L4.000 – RECORDS

N/A ☐

Does the tissue dispensing service record all steps in the process so that all steps can be traced? Yes ☐ No ☐ N/A ☐

How long are records maintained? _____

L4.100 Tissue Receipt Records

Does each tissue specimen have a tissue identification number? Yes ☐ No ☐ N/A ☐

Do records contain the appropriate information? Yes ☐ No ☐ N/A ☐

L4.200 Dispensing Records

Is the disposition of tissue documented? Yes ☐ No ☐ N/A ☐

Is appropriate information (listed in this standard) recorded? Yes ☐ No ☐ N/A ☐

Where is the information maintained? _____
_____

L5.000 ADVERSE OUTCOMES

N/A ☐

How are reports of potential adverse outcomes, suspected transmitted disease, or other complications reported and evaluated and by whom?

_____
_____
_____

☐ Review the adverse outcome procedure. Procedure number _____

L6.000 RECALLS

N/A ☐

Are there written procedures for the recall of tissue? Yes ☐ No ☐ N/A ☐

Is AATB notified within 15 days of recalls? Yes ☐ No ☐ N/A ☐

☐ Review the recall procedure. Procedure number: _____

AATB STANDARDS SECTION M
TISSUE DISTRIBUTION INTERMEDIARIES

N/A ☐

M1.000 TISSUE DISTRIBUTION INTERMEDIARIES - GENERAL

N/A ☐

(An agent who acquires and stores distributed tissue for further distribution and performs no other tissue banking activities.)

Do you acquire distributed tissue for storage and further distribution? Yes ☐ No ☐ N/A ☐

How do you ensure appropriate policies and procedures are implemented to ensure traceability?

_____
_____
_____

M2.000 STORAGE

N/A ☐

M2.100– Storage - General

How does the facility ensure conformance with distributing bank guidelines?

_____
_____
_____

M2.200 – Equipment

Are refrigerators maintained, calibrated, and monitored? Yes ☐ No ☐ N/A ☐

☐ Review QC procedures for refrigerator maintenance, calibration, and monitoring.

✔ Randomly select maintenance records for a refrigerator.
Is the information complete? Yes ☐ No ☐ N/A ☐
Is the maintenance schedule maintained? Yes ☐ No ☐ N/A ☐
Maintenance log reviewed: _____

☐ Procedure numbers _____

M2.300 – Labeling

How does the facility ensure tissue is not relabeled or the label altered?

_____
_____
_____

M3.000 DISTRIBUTION – GENERAL

N/A ☐

☐ Review the procedures for receipt of tissue orders, unit selection, final container and/or package inspection, shipping, and transportation of tissue for transplantation.

Are procedures current and complete? Yes ☐ No ☐ N/A ☐

M3.100 Tissue Distribution Restrictions

How does the facility ensure requests for tissue are received from appropriate sources?

_____
_____
_____

M3.200 Transfer of Tissue to Other Banks/Dispensing Services

How do you ensure all appropriate documentation is forwarded with the tissue?

_____
_____
_____

M3.300 Requests for Donor Status and Tissue Processing Information

How do you ensure donor information is released according to standards and your SOPM?

_____
_____
_____

M3.400 Distribution Records

Do you maintain appropriate distribution records? Yes ☐ No ☐ N/A ☐

How does the facility ensure appropriate information is documented in the distribution records (see standard M3.400)?

_____
_____
_____

M3.500 Tissue Disposal

How does the facility ensure tissue is disposed of in such a manner as to minimize hazards to staff and the environment?

_____
_____
_____

Is documentation of notification of the final disposition of tissue recorded? Yes ☐ No ☐ N/A ☐

M4.000 PACKAGING AND SHIPPING

N/A ☐

M4.100 Tissue Storage Environment

Are specific environmental conditions required for storing tissue? Yes ☐ No ☐ N/A ☐

How does the facility ensure environmental conditions are maintained during transit?

_____
_____
_____

M4.200 Validation and Packaging Expiration

Do tissue to be shipped require specific environmental conditions other than ambient temperature? Yes ☐ No ☐ N/A ☐

If yes, was the validation study for determining the capability of the transport container to maintain environmental conditions documented? Yes ☐ No ☐ N/A ☐

☐ Review the validation procedure. Procedure number _____

M4.300 Quality Control

If required, is quality control monitoring of shipping and packaging containers performed? Yes ☐ No ☐ N/A ☐

Where are the QC checks documented?

_____
_____
_____

M4.400 Final Inspection

Is a thorough and appropriate final inspection performed for each package? Yes ☐ No ☐ N/A ☐

☐ Review procedure(s). Procedure number_____

M4.500 Transportation

How is the mode of transportation of tissue selected?

_____
_____
_____

M5.000 RETURN OF TISSUE

N/A ☐

Does the facility accept returned tissue? Yes ☐ No ☐ N/A ☐

If yes, how does the facility ensure the requirements in M5.000 are followed?

_____
_____
_____

☐ Review the return of tissue procedure. Procedure number _____

M6.000 Recalls

N/A ☐

M6.100 Recall Records

Is recall information appropriately documented? Yes ☐ No ☐ N/A ☐

Is all required information included in the documentation?

- Reason for recall Yes ☐ No ☐ N/A ☐
- Steps taken to retrieve recalled tissue Yes ☐ No ☐ N/A ☐
- Documentation of all recall communication Yes ☐ No ☐ N/A ☐
- Quarantining steps Yes ☐ No ☐ N/A ☐
- Final disposition of tissue Yes ☐ No ☐ N/A ☐
- Corrective actions recommended and implemented Yes ☐ No ☐ N/A ☐
- Documentation of review Yes ☐ No ☐ N/A ☐

How long is recall information retained?

_____
_____
_____

Is AATB notified of recalls within 15 days? Yes ☐ No ☐ N/A ☐

☐ Review the recall procedure. Procedure number _____

M7.000 RECORDS

N/A ☐

Does the tissue dispensing service record all steps in the process so that all steps can be clearly traced? Yes ☐ No ☐ N/A ☐

How long are records maintained? _____
_____
_____

M7.100 Tissue Receipt Records

Does each tissue specimen have a tissue identification number? Yes ☐ No ☐ N/A ☐

Do records contain the appropriate information as indicated in this standard?

- Name and address of tissue supplier Yes ☐ No ☐ N/A ☐
- Description of tissue and quantity received Yes ☐ No ☐ N/A ☐
- Date of tissue receipt Yes ☐ No ☐ N/A ☐
- Condition of tissue upon receipt Yes ☐ No ☐ N/A ☐
- Expiration date of tissue (if applicable) Yes ☐ No ☐ N/A ☐

M7.200 Distribution Records

When tissue is transferred to another facility
is all appropriate information recorded? Yes ☐ No ☐ N/A ☐

How does the facility ensure all appropriate information is recorded?

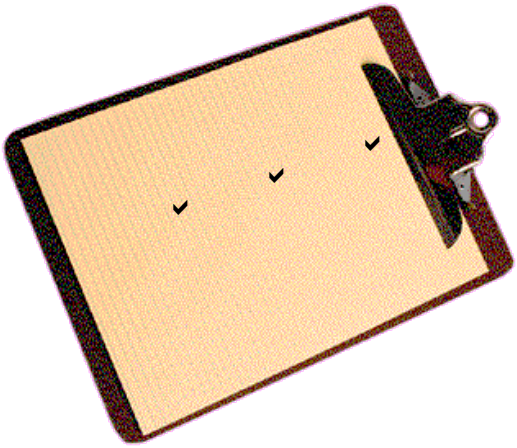
_____
_____
_____

M8.000 ADVERSE OUTCOMES

N/A ☐

Are reports of adverse outcomes, transmitted disease, or other complications
reported to the supplier of the tissue in a timely fashion? Yes ☐ No ☐ N/A ☐

DONOR CHART CHECKLIST



Directions: The following checklist is for use as a reference when reviewing individual donor charts. The "required document content" is the specific information that the AATB inspector will be looking for as objective evidence to evaluate compliance with *AATB Standards*. In order to be compliant, this information shall be appropriately documented.

Bank _____

Donor No. _____

Reviewer _____

Date _____

DONOR RECORD SAMPLING PLAN
INDEX VALUES
(ASSOCIATED AQLS)

	.010	.015	.025	.040	.065	.10	.15	.25	.40	.65	1.0	1.5	2.5	4.0	6.5	10.0
Lot Size	**Sample Size**															
2 to 8	*	*	*	*	*	*	*	*	*	*	*	*	5	3	2	2
9 to 15	*	*	*	*	*	*	*	*	*	*	13	8	5	3	2	2
16 to 25	*	*	*	*	*	*	*	*	*	20	13	8	5	3	3	2
26 to 50	*	*	*	*	*	*	*	*	32	20	13	8	5	5	5	3
51 to 90	*	*	*	*	*	*	80	50	32	20	13	8	7	6	5	4
91 to 150	*	*	*	*	*	125	80	50	32	20	13	12	11	7	6	5
151 to 280	*	*	*	*	200	125	80	50	32	20	20	19	13	10	7	6
281 to 500	*	*	*	315	200	125	80	50	48	47	29	21	16	11	9	7
501 to 1200	*	800	500	315	200	125	80	75	73	47	34	27	19	15	11	8
1201 to 3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13	9
3201 to 10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15	9
10,001 to 35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15	9
35,001 – 150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15	9
150,001 to 500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15	9
500,001 and over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15	9

*** Indicates that entire lot must be inspected**

EXAMPLE: You have one year's worth of records to review. There are 221 records that comprise the year's total (year's total = population = Lot Size). Look down the LOT SIZE column until you come to "151 - 280," then move across the row to the highlighted column. 20 is the number of records that need to be reviewed. If the population is 400 records, then the sample quantity is 29, if 510, then the sample quantity is 34.

DONOR CHART REVIEW

(Revised August 2010)

Review the donor chart for completeness.

Donor Chart Number(s): _____

Type of Review: ☐ Completeness/Accuracy Audit ☐ Tracer Audit

Reviewer/Date: _____

Required Document	***AATB Standards***	**Yes**	**No**	**N/A**	**Required Document Content** (*Check yes, no, n/a upon review and verification*)
1a. Document of Gift/Authorization or Informed Consent (Anatomical Gift Form)	C1.100 D2.000 D2.100 D2.300 D2.400 D2.500 D2.600				Are required signatures present? • Authorizing/Consenting Person, if applicable • Person obtaining Document of Gift/Authorization or Informed Consent • Witness (if applicable)
1b.					Is authorization present from the Authorizing/Consenting Person, to acquire tissue and make available for transplantation?
1c.					✔ Verify that a few selected facts on the Document of Gift/Authorization or Informed Consent and/or other donor records are accurate. • Selected authorization/consent fact(s) verified (list) • Other fact(s) verified (list)
1d.					✔ If authorization/consent is obtained via telephone, verify that authorization/consent is: • Witnessed (if applicable) • Recorded
1e.					✔ If authorization/consent is obtained via facsimile or electronically, verify that the person obtaining authorization/consent is available to the authorizing/consenting person to respond to questions.

Donor Chart Number(s):_____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
2a. Donor Physical Examination Form	D4.200				✔ Verify that one or more facts are correct (or you may choose to verify something else in the chart). _____ ✔ Verify name of examiner: ✔ Verify completion of the form
2b. Donor Risk Assessment Interview	D4.220				Are the following items present? • Donor Name • Relationship of donor to Authorizing/Consenting Person • Name of the interviewee • Name of the interviewer ✔ Verify completion of all applicable questions.
2c. Preliminary Donor Medical History	D4.230				✔ Verify that a preliminary review of the donor history was conducted. (May be in the form of a donor work-up sheet or a donor referral.)
2d. Medical Records	D4.230				✔ Verify that relevant medical records or a summary of relevant medical records is available for Medical Director review.
2e. Donor Autopsy Report	D4.240				✔ When applicable, verify autopsy report is a record in the donor chart or is being pursued.
2f. Plasma Dilution	D4.352				✔ When applicable, verify completion of the plasma dilution worksheet.

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
2g. Blood Testing	D4.354				✔ Verify testing results. • anti-HIV-1 • anti-HIV-2 • Nucleic acid test (NAT) for HIV-1 • Hepatitis B (HBsAg) • Total antibody to hepatitis B core antigen (anti-HBc- total meaning IgG and IgM) • Hepatitis C (anti-HCV) • Nucleic acid test (NAT) for HCV • anti-HTLV-I (if applicable) • anti-HTLV-II (if applicable) • Syphilis • Other
2h. Age Criteria	D4.400				Are age requirements met?
3a. Donor Recovery	C1.100 D5.000				Is donor recovery documentation present and complete?
3b. Donor Identity	D5.120				✔ Verification of donor identity ✔ Source of donor verification
3c. Recovery Records	D5.600				✔ For tissue other than autologous tissue, verify recovery records contain: • Name and address of recovery agency • Date, time, and staff involved in the recovery • Location of the tissue donation within the recovery site facility, if relevant • Donor name, age, and sex • Type, lot number, manufacturer, and expiration date of supplies and reagents used to recover, rinse, and transport tissue • Specific tissues recovered

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
3d. Tissue Recovery Cultures	D5.521 K2.210				✔ Verify that recovery cultures (if applicable) are obtained prior to exposing tissue to antibiotics.
3e. Post-Recovery	D5.600 D5.900				✔ Verify post-recovery records • Documentation of deceased donor reconstruction • Final disposition
3f. Sharing of Records	D4.500				✔ Verify that information has been shared as required. Is the information system: • Timely • Clear • Documented
3g. Certified Death Certificate (if applicable)	D4.230				✔ Is a certified copy of the death certificate obtained/requested if the donor's death did not occur in a hospital, or when no third party records are available that can establish a likely cause of death and no autopsy is performed?
3h. Cause of Death	D4.230				✔ How is the cause of death documented? Is this documentation adequate? (Indicate the document reviewed).

The following references may be useful when verifying selected facts (e.g., cause of death, donor age, primary physician's telephone, etc.) in donor records:

- ✔ *Google NOK phone number (don't call)*
- ✔ *Check NOK address in White Pages or www.addresses.com*
- ✔ *Look up obituaries:*
  - *www.legacy.com/Obituaries.asp (free)*
  - *www.Deathlibrary.com/DeathRecords.html (fee for this service)*
- ✔ *Funeral home obituaries can be posted on the Internet and can be used to check for donor's name.*
- ✔ *www.currentobituary.com (free)*
- ✔ *State index of newspapers, obituary search engines, obit indexes, and death records (free) www.ancestorhunt.com/obituary_search_engines.html*

Attachment 1

G3.120 Content

Each container label shall include the tissue identification number.

The following information shall also be included on the container label unless space limitations require use of a corresponding insert:

1) Descriptive name of the tissue;

2) Name(s) and address(es) of tissue bank(s) responsible for determining donor suitability, processing and distribution; (Should more than two banks be involved, the name of all banks are required but the address is only required for the bank determining donor suitability.)

3) Expiration date (if applicable), including the month and year;

4) Acceptable storage conditions, including recommended storage temperature and acceptable storage temperature range;

5) Disinfection or sterilization procedure utilized (if applicable);

6) Preservative (if utilized) and/or method of preservation (if applicable);

7) Quantity of tissue expressed as volume, weight, dimensions, or a combination of these units of measure, if applicable;

8) Potential residues of processing agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethyl sulfoxide); and

9) The statement "See package insert".

G3.130 Additional Labeling Requirements

(A) The following information shall be included on the container label for autologous tissue unless space limitations require use of a corresponding insert:

1) The donor classification statement "AUTOLOGOUS DONOR";

2) The patient's name and, if available, the name of the facility where the patient is being transplanted and the patient's hospital registration number (or, if unavailable, social security number, birth date, or similar identifying information);

3) A label or attached tag "FOR AUTOLOGOUS USE ONLY";

4) If infectious disease testing or donor screening is not complete or has not been performed, a label indicating “NOT EVALUATED FOR INFECTIOUS SUBSTANCES” is required, or

5) If infectious disease testing was performed and any results were positive, or if donor screening was performed and risk factors identified, then labeling with a “BIOHAZARD” label is required.

Attachment 2

G3.210 Summary of Records Content

A *Summary of Records* is required when donor suitability determination has been completed and shall include:

1) A statement that the tissue was prepared from a donor determined to be suitable based on the results of screening and testing. All results of relevant communicable disease tests performed on specimens from the donor and used for release of tissue shall be listed. Relevant tests include those tests that are required (see D4.354 Required Infectious Disease Tests). If a test for anti-HTLV I and/or II was performed, it must be reported. To clarify expectations and to offer an example, the CMV test result used must be listed for reproductive tissue; and

2) A statement that the communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS); and

3) The name and address of the establishment that made the donor suitability determination.

G3.220 Package Insert Content

The *Summary of Records* may be included in the *Package Insert*. The *Package Insert* shall contain the following information:

1) A statement limiting use to specific health professionals (e.g., physicians, dentists, and/ or podiatrists);

2) A statement that the tissue is intended for use in one patient, on a single occasion only, or as is applicable for *Reproductive Tissue*;

3) Known contraindications (if any) to the use of the tissue;

4) Warnings and list of known possible significant adverse reactions;

5) A statement that *Adverse Outcomes* potentially attributable to the tissue must be reported promptly to the tissue supplier;

6) Presence of known sensitizing agents (if any);

7) A statement that indicates that the tissue may transmit infectious agents;

8) A statement, if applicable, that the tissue may not be *Sterilized* or re-sterilized.

9) Dosage information (if applicable);

10) Description of how the tissue was supplied (e.g., frozen, lyophilized, irradiated);

11) Type of antibiotics present (if applicable);

Attachment 2 (Continued)

12) Concentration of preservative(s) and/or cryoprotectant(s) in final package solution (if applicable);

13) Instructions for opening the *Package* and/or *Container*;

14) Instructions for preparation of tissue for transplantation;

15) Expiration time of tissue following reconstitution;

16) Instructions indicating that once a *Container* seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded;

17) Recommended storage conditions and *Tolerance Limits*;

18) Special instructions required for the particular tissue (e.g., ''DO NOT FREEZE'');

19) A statement that it is the responsibility of the *Tissue Dispensing Service, Tissue Distribution Intermediary,* and/or *End-User* clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further *Distribution* or transplant and that *Recipient* records must be maintained for the purpose of tracing tissue post-transplantation;

20) A statement that the tissue is ''DONATED HUMAN TISSUE,'' when applicable; and

21) Date of issue or revision of the *Package Insert*.

NOTE: Except for directed reproductive donations and autologous tissues, the accompanying records required by this section must not contain the donor's name or other personal information that might identify the donor.

(C, V) Inserts for cardiac and vascular tissue shall contain the following additional information:

1) Warning against using a graft if there is evidence that the *Container* has broken or the contents have thawed;

2) Statement that the tissue may not be *Sterilized*;

3) Donor age (and blood type, if available);

4) Date of dissection or *Preservation*;

5) Tissue *Warm Ischemic Time*;

6) Tissue *Cold Ischemic Time*;

7) Graft sizes (e.g., diameter and length);

8) Graft physical descriptions and evaluations, including description of imperfections and evaluation criteria;

9) The type of *Cryoprotectant* (if applicable) and clear statement regarding the possibility of residuals;

10) A description of the temperature-sensitive nature of the grafts; and

11) Instructions for preparation of tissue for use.

Center-specific protocols shall be established for control of proper thawing, removal of *Cryoprotectant*, and restoration of isotonic balance within the *Cryopreserved* tissue. These protocols shall be provided with each cardiovascular *Allograft* distributed for transplantation.

The preparation instructions shall be sufficiently detailed and unambiguous to allow operating room personnel of average skill to follow and complete the procedure successfully.