

American Association of Tissue Banks

Self-assessment *T*ool / Audit *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

Check one

AUDIT CONFIRMATION

- 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
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Signature of Person Completing the Audit Confirmation	Date
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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.

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 No N/A

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.

B1.600 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

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

C4.000 PROCESSING RECORDS

N/A

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

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 than 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*)
- Physical evidence for risk of or evidence of

Yes No N/A

- 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 vaccinia keratitis Yes No N/A
- Corneal scarring consistent with vaccinia 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 C² 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 Europe⁴ 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 xenotransplantation⁵ (i.e. receipt of a xenotransplantation product⁶ or who has had intimate contact⁷ 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 person³;
- 26) Persons who have had recent smallpox vaccination (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact⁸ 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.

¹RELEVANT 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 gonorrhoea*.

²CLINICALLY 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.

³Tissue 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.

⁴European 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.

⁵XENOTRANSPLANTATION – 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.

⁶XENOTRANSPLANTATION 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.

⁷XENOTRANSPLANTATION 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.

⁸CLOSE 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-banded 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)
(in accordance with federal, state, and/pr local laws and/or regulations.) Yes No N/A
- 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
- 2) Date and time of movement into storage at the processing facility
- 3) Personnel involved

Yes No N/A
Yes No N/A
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

E1.310 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 No 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 (°C)*
Cardiac and Vascular	Frozen, cryopreserved	-100°C or colder
Dura	Lyophilized	Ambient***
Musculoskeletal	Refrigerated	1-10°C
	Frozen, cryopreserved and non-cryopreserved (temporary storage less than 6 months)	-20°C to -40°C **
	Frozen, cryopreserved and non-cryopreserved (long term storage)	-40°C or colder
	Lyophilized	Ambient***
Reproductive	Frozen, cryopreserved	LN ₂ (Liquid or Vapor Phase)
Skin	Refrigerated	1-10°C
	Frozen, cryopreserved	-40°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°C to - 40°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
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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 <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| • Unit selection | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| • Final container and/or package inspection | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| • Shipping and transportation of tissue for transplantation | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

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

**AATB STANDARDS SECTION J
GENERAL OPERATIONS**

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) (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 No N/A

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?

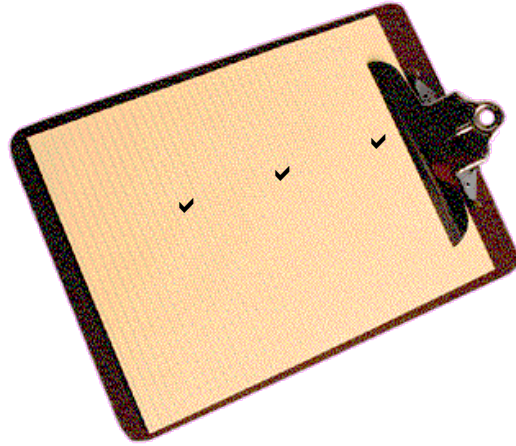
M8.000 ADVERSE OUTCOMES

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)**

Lot Size	Sample Size															
	.010	.015	.025	.040	.065	.10	.15	.25	.40	.65	1.0	1.5	2.5	4.0	6.5	10.0
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? <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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				<ul style="list-style-type: none"> ✓ 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				<p>Are the following items present?</p> <ul style="list-style-type: none"> • Donor Name • Relationship of donor to Authorizing/Consenting Person • Name of the interviewee • Name of the interviewer <p>✓ Verify completion of all applicable questions.</p>
2c. Preliminary Donor Medical History	D4.230				<ul style="list-style-type: none"> ✓ 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				<ul style="list-style-type: none"> ✓ Verify that relevant medical records or a summary of relevant medical records is available for Medical Director review.
2e. Donor Autopsy Report	D4.240				<ul style="list-style-type: none"> ✓ When applicable, verify autopsy report is a record in the donor chart or is being pursued.
2f. Plasma Dilution	D4.352				<ul style="list-style-type: none"> ✓ 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				<ul style="list-style-type: none"> ✓ Verify testing results. <ul style="list-style-type: none"> • 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				<ul style="list-style-type: none"> ✓ Verification of donor identity ✓ Source of donor verification
3c. Recovery Records	D5.600				<ul style="list-style-type: none"> ✓ For tissue other than autologous tissue, verify recovery records contain: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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;

Attachment 2 (Continued)

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.