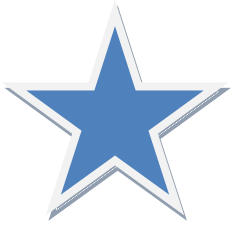
American Association of Tissue Banks

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

REPRODUCTIVE

Based on AATB *Standards for Tissue Banking*, 12th edition 2008

Includes Changes (in blue) from:
AATB News Release 11/11/2009
AATB Bulletin 10-05
AATB Accreditation Policies



August 2010

August 19, 2010

AUDIT CONFIRMATION

Check one

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

For External Audits:

Name and address of outside facility audited:

_____

_____

_____

This Audit Confirmation is to be submitted to AATB as follows:

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

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

Facility Name: _____

Address: _____

_____

_____

_____ _____ _____

Individual Completing the Audit Confirmation Title Telephone

_____ _____

Signature of Person Completing the Audit Confirmation Date

Activities audited: _____

_____

_____

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

INSTRUCTIONS FOR COMPLETING THE STAR

USES:

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

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

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

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

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

COMPLETING THE FORM:

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

AATB STANDARDS SECTION B
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

N/A ☐

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

R = Reproductive, A = Autologous LD = Living Donor

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

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

B1.200 Governing Body

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

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

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

_____

B1.300 Medical Scientific Support

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

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

_____

B1.400 Satellite Facilities

Do you have satellite facilities? Yes □ No □ N/A □

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

□ Review audits of your satellite facilities to make sure they are operating according to your SOPM.
□ Show the administrative relationships on your bank's organizational chart.

B1.500 Multi-Facility Tissue Banking

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

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

_____
_____
_____

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

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

_____
_____
_____

B1.510 Written Agreements/Contracts

Does the 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 □

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 □

□ Review the contract(s)

Bl.521 Inspections/Audits of Other Facilities

Do you ensure that all other tissue banking organizations under contract, agreement, or other arrangement, performing activities/services for you, comply with AATB *Standards*, federal regulations, and applicable state and/or local laws, before executing a contract or agreement with them? 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 believe that the entity performing activities/services for you may no longer be in compliance with AATB *Standards*, federal regulations, applicable state and/or local laws?

_____

_____

_____

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

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

Bl.600 Contracted Laboratory Services

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 contracts 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
B2.122 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 procedures regarding donor suitability criteria and technical functions? 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 ☐

If yes, 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

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

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 ensuring 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

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?

_____
_____
_____

Are the names of the donors encoded? Yes ☐ No ☐ N/A ☐

How do you ensure only the Director or designee can link the donor's name to the identification code?

_____
_____
_____

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 AATB standards, federal, state, and/or local laws? Yes □ No □ N/A □

C1.400 Traceability

Are unique donor identifiers 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 donor identifier?

_____
_____
_____

Are 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

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 □

□ 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 □

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

_____
_____
_____

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

C3.000 DONOR RECORDS TO BE MAINTAINED

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

_____
_____
_____

Do donor records include documentation of:

- Informed consent Yes ☐ No ☐ N/A ☐
- Relevant medical records Yes ☐ No ☐ N/A ☐
- Results of laboratory screening tests Yes ☐ No ☐ N/A ☐
- Outcome of prior assisted reproductive procedures Yes ☐ No ☐ N/A ☐

Do records include the following personal attribute information:

- Height Yes ☐ No ☐ N/A ☐
- Weight Yes ☐ No ☐ N/A ☐
- Eye color Yes ☐ No ☐ N/A ☐
- Hair color Yes ☐ No ☐ N/A ☐
- Complexion Yes ☐ No ☐ N/A ☐
- Racial group Yes ☐ No ☐ N/A ☐
- Body type Yes ☐ No ☐ N/A ☐

C4.000 PROCESSING RECORDS

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

If yes, 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 □

Do the Director and Medical Director establish procedures for recruiting, accepting /excluding potential reproductive donors and client depositor reproductive tissue? Yes □ No □ N/A □

□ What donor referral source is used? (If applicable)

_____
_____
_____

Do the Director and Medical Director establish procedures for accepting client depositors and for recruiting or excluding potential reproductive tissue donors? Yes □ No □ N/A □

D2.000 INFORMED CONSENT

D2.100 Authorization Requirements

Does the tissue bank obtain informed consent in writing, in accordance with AATB *Standards*, anatomical gift acts and federal, state, and/or local laws? Yes □ No □ N/A □

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

□ Review consent procedure. Procedure number _____

D2.200 Consent Conditions

How do you ensure informed consent is obtained according to procedures?

_____
_____
_____

□ Review informed consent training procedures to make sure individuals are trained not to use coercion.

D2.300 Signatures

Reference Donor Chart Checklist (attached to the back this document) and Appendix III of *AATB Standards.*

Is permission obtained to acquire reproductive cells or tissues from the donor or client depositor? Yes □ No □ N/A □

How do you ensure that informed consent is adequate regardless of the method used to obtain consent?

_____
_____
_____

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

Is the sampling performed by someone other that the person obtaining consent? Yes ☐ No ☐ N/A ☐

D2.500 Informed Consent for Living Donors

Do you acquire tissue from living donors? Yes □ No □ N/A □

How do you ensure that appropriate consent has been obtained?

_____
_____
_____

Does the informed consent indicate the donor's/client depositor's name and address and that required records will be kept on file by the bank? Yes □ No □ N/A □

□ Review consent procedure. Procedure number _____

D3.000 MONETARY COMPENSATION OF DONORS

Does the facility have a policy regarding monetary compensation? Yes □ No □ N/A □

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

D4.000 DONOR SUITABILITY

D4.100 General

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

Do the Director and Medical Director establish the criteria for accepting client depositors and donors and potential reproductive cells? Yes □ No □ N/A □

D4.200 Donor Assessment

D4.210 Physical Examination

Does the physical examination include assessment for any evidence of:

- Sexually transmitted diseases (genital ulcerative disease, herpes simplex, syphilis, chancroid) Yes □ No □ N/A □
- Physical evidence for risk of or evidence of syphilis (genital lesion, rash, skin lesion *(non-genital)* Yes ☐ No ☐ N/A ☐
- For male donor: anal intercourse including perianal condyloma *(insertion trauma, perianal lesions)* Yes □ No □ N/A □
- Needle track marks Yes □ No □ N/A □
- Disseminated lymphadenopathy Yes □ No □ N/A □
- Unexplained oral thrush Yes □ No □ N/A □
- HIV (blue or purple spots consistent with Kaposi's sarcoma) Yes □ No □ N/A □
- Needle tracks including exam of tattoos, which may cover needle tracks Yes □ No □ N/A □
- Hepatitis Yes □ No □ N/A □
- Jaundice Yes □ No □ N/A □
- Hepatomegaly Yes □ No □ N/A □

- Large scab consistent with recent smallpox immunization Yes ☐ No ☐ N/A ☐
- Eczema vaccination *(lesion/scab)* Yes ☐ No ☐ N/A ☐
- Generalized vesicular rash, generalized vaccinia (rash) Yes ☐ No ☐ N/A ☐
- Severely necrotic lesion consistent with vaccinial keratitis Yes ☐ No ☐ N/A ☐
- Corneal scarring consistent with vaccinial keratitis Yes ☐ No ☐ N/A ☐

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

_____

_____

_____

D4.211 Physical Examination

For all anonymous and directed semen and oocyte donors, is the physical examination performed by the Medical Director or physician designee, or by a physician involved with the donor's medical care, or his/her designee? Yes □ No □ N/A □

□ Review physical exam procedure. Procedure number _____

D4.211 Physical Examination

Is a physical examination performed on all anonymous and directed semen and oocyte donors? Yes ☐ No ☐ N/A ☐

Is a repeat physical examination performed on anonymous semen donors at least every six months while the donor is actively collecting samples in the program? Yes ☐ No ☐ N/A ☐

Is the information obtained used to determine evidence of high risk behavior and overall general health of the donor? Yes ☐ No ☐ N/A ☐

D4.220 Donor Risk Assessment

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 that is based on AATB *Standards*, current federal regulations, and guidance? Yes □ No □ N/A □

Does the risk assessment include a review of:

- Alcohol use Yes □ No □ N/A □
- Drug use Yes □ No □ N/A □
- Chemical and/or radiation exposure
- Sexually transmissible diseases in the donor and partners Yes □ No □ N/A □
- Family medical history and genetic background Yes □ No □ N/A □

Is a donor excluded unless criteria established by the Medical Director are met? Yes □ No □ N/A □

Is an abbreviated donor screening obtained at each repeat donation and reviewed by a responsible person? Yes □ No □ N/A □

Does the abbreviated screening determine and document any changes in the donor's medical, social, and sexual history (including risk factors since the previous donation) that would make the donor ineligible? Yes □ No □ N/A □

□ Review the abbreviated screening form, does it contain all required

Information? Yes □ No □ N/A □

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

Behavior/History Exclusionary Criteria

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[1]RELEVANT COMMUNICABLE DISEASE AGENT OR DISEASE (RCDAD) – a potentially infectious *Microorganism*, virus, or other disease agent that may pose a risk of transmission to *Recipients* of, or those who come in contact with, tissues. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential donor population; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for donor specimens has been cleared, approved, or *FDA*-licensed, and is available. They can also be those disease agents or diseases that could place potential donors

and/or *Recipients* at risk for infection due to accidental or intentional release. RCDADs applicable to all cell and/or tissue donors are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, SARS (when applicable), WNV, vaccinia, and sepsis. Donors of viable, leukocyte-rich tissues must additionally consider HTLV I/II, and donors of reproductive tissues must generally consider *Chlamydia trachomatis* and *Neisseria gonorrhea*.

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

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

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

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

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

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

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

Sources:

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

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

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

D4.221 Family History and Genetic Background

Is a minimum of a three-generation family history elicited from each prospective donor? Yes ☐ No ☐ N/A ☐

How do you ensure that the genetic history is evaluated by an individual with appropriate clinical genetics education and/or training?

_____
_____
_____

Does any condition in a prospective donor or donor's family history that would pose a risk or producing an offspring with a genetic disease or defect greater than the risk in the general population disqualify the donor (except as noted in this standard)? Yes ☐ No ☐ N/A ☐

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 ☐

If the donor's death did not occur in a hospital and third party records are not available that can be used to establish likely cause of death, and no autopsy was performed, is a certified copy of the death certificate included in the donor record? 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 implantation, does the Medical Director or licensed physician designee determine donor suitability? 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 from donors 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

_____
_____
_____

Are semen donors with evidence of the following excluded:

- infectious skin disease that creates a risk of contamination of the semen — Yes □ No □ N/A □
- Chlamydia trachomatis (within past 12 months) unless the reproductive tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract — Yes □ No □ N/A □
- Neisseria gonorrhea (within past 12 months) unless the reproductive tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract — 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 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 history 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 □

For oocytes, is the donor blood specimen collected within 30 days prior to oocyte retrieval or within 7 days post donation? Yes □ No □ N/A □

For sperm, is the donor blood specimen collected within 7 days of of the initial semen collection? Yes □ No □ N/A □

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

_____
_____
_____

□ Review collection of donor blood procedure. Procedure number _____

D4.353 Infectious 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?

_____
_____
_____

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 including testing for N. gonorrhea and Chlamydia trachomatis, unless tissues are collected by a method that ensures freedom from contamination by infectious disease organisms that may be present in the genitourinary tract? Yes □ No □ N/A □

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

Are anonymous and directed semen donors also tested for total antibody to cytomegalovirus (anti-CMV – total, meaning IgG and IgM)? Yes □ No □ N/A □

Prior to use, are client depositors tested for; anti-HIV-1, anti-HIV – 2, HBsAg and anti – HCV? Yes □ No □ N/A □

Do all oocyte donors undergo required testing within 30 days prior to egg retrieval or within 7 days post donation? Yes □ No □ N/A □

Are samples for infectious disease testing of anonymous and directed semen donors obtained within 7 days of initial semen collection? Yes □ No □ N/A □

D4.355 Interpretation of Infectious Disease Test Results

Is the final disposition of reproductive tissue from donors based upon the interpretation of all blood infectious disease test results? Yes □ No □ N/A □

When required test results are positive or repeatedly reactive, are protocols established (as described in F2.200 – Special Circumstances in Release Reproductive Tissue) Yes □ No □ N/A □

How does the facility document the use of client depositor and/or directed donor tissues in cases where required test results are positive or repeatedly reactive?

_____
_____
_____

How does the bank comply with the CMV requirements of this standard?

_____
_____
_____

How does the bank comply with anti-HTLV-I and anti-HTLV-II testing requirements?

_____
_____
_____

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 samples from unsuitable donors archived? Yes □ No □ N/A □

□ Review archive storage area, log books, etc.

D4.360 Repeat Testing of Living Donors

Is appropriate retesting performed for directed and anonymous reproductive semen donors that includes:

anti-HIV-1 Yes □ No □ N/A □
anti-HIV-2 Yes □ No □ N/A □
HIV – 1 NAT Yes □ No □ N/A □
HBsAg Yes □ No □ N/A □
anti-HTLV-I (if applicable) Yes □ No □ N/A □
anti-HTLV-II (if applicable) Yes □ No □ N/A □
anti-HCV Yes □ No □ N/A □
HCV – NAT Yes □ No □ N/A □
anti-HBc Yes □ No □ N/A □
anti-CMV Yes □ No □ N/A □
syphilis Yes □ No □ N/A □

Is retesting performed at least every six months while the semen donor remains an active participant in the donor program and after any lapse exceeding 6 months? Yes □ No □ N/A □

For directed or anonymous donation of embryos created by sexually intimate client depositors, are embryos quarantined for at least 6 months from the day of creation? Yes □ No □ N/A □

After 6 months and prior to release of embryos for transfer, is each sexually intimate client depositor tested for antibodies to HIV-1, HIV-2, HCV, HBc, HBsAg, and for HIV-1 NAT, HCV NAT, and syphilis? Yes □ No □ N/A □

In addition, is the male tested for:

- anti-CMV Yes □ No □ N/A □
- anti-HTLV-I Yes □ No □ N/A □
- anti-HTLV-II? Yes □ No □ N/A □

For directed or anonymous donated embryos created using one anonymous or directed egg or sperm donor, are embryos quarantined for at least 6 months from the date of creation? Yes □ No □ N/A □

After 6 months and prior to release of embryos for transfer, is the client depositor tested for antibodies to HIV-1, HIV-2, HBc, HBsAg, HCV, and for HIV-1 NAT, HCV NAT and syphilis? Yes □ No □ N/A □

In addition, if the client depositor is male, is the male tested for:

- anti-CMV Yes □ No □ N/A □
- anti-HTLV-I Yes □ No □ N/A □
- anti-HTLV-II? Yes □ No □ N/A □

Is a Summary of Records obtained for the donor? Yes □ No □ N/A □

If the embryo was acquired from a non-accredited facility and a directed sperm donor was used without a 6 month quarantine and re-test, is the directed donor re-tested following a 6-month quarantine for antibodies to HIV-1, HIV-2, HBsAg, HBc, HCV, and for HIV-1 NAT, HCV NAT, and syphilis? Yes □ No □ N/A □

In addition, is the male tested for:

- anti-CMV Yes □ No □ N/A □
- anti-HTLV-I Yes □ No □ N/A □
- anti-HTLV-II? Yes □ No □ N/A □

For directed or anonymous donated embryos created using both

an anonymous or directed egg and sperm donor, is a summary of records obtained for both donors? Yes □ No □ N/A □

If the embryo was acquired from a non-accredited facility and a directed sperm donor was used without a 6 month quarantine and re-test, is the directed donor re-tested following a 6-month quarantine for antibodies to HIV-1, HIV-2, HBsAg, HBc, HCV, and for HIV-1 NAT, HCV NAT, and syphilis? Yes □ No □ N/A □

In addition, are the following tests performed:

- anti-CMV Yes □ No □ N/A □
- anti-HTLV-I Yes □ No □ N/A □
- anti-HTLV-II? Yes □ No □ N/A □

D4.370 Semen Analysis

Is appropriate sperm quality testing done on semen donor cells and/or tissue? Yes □ No □ N/A □

Are pertinent test results made available to the client depositor's physician? Yes □ No □ N/A □

D4.400 Age Criteria

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

- Semen _____
- Embryos _____

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 ☐

D5.000 RETRIEVAL POLICES AND PROCEDURES

D5.100 Verification Procedures
D5.110 Informed Consent

Prior to retrieval, how does staff ensure that informed consent has been obtained and documented?

_____
_____
_____

□ Review the procedure. Procedure number _____

D5.120 Donor Identity

How does retrieval staff perform donor identity verification?
(Reference Donor Chart Checklist in back of STAR)

_____
_____
_____

D5.200 Donor Identification Number

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

_____
_____
_____

At the time of collection, is the collection container labeled with:

- Date of collection Yes □ No □ N/A □
- Time of collection or retrieval Yes □ No □ N/A □
- Donor's identification or name for client depositor Yes □ No □ N/A □

D5.310 Tissue Retrieval – General

Is collection of anonymous donor semen specimens made at the semen bank? Yes □ No □ N/A □

D5.700 Post-Retrieval Packaging

Are reproductive cells deposited individually into a pre-labeled container? Yes □ No □ N/A □

Is the container labeled with:

- Donor identification Yes □ No □ N/A □
- Date Yes □ No □ N/A □
- Type of cells Yes □ No □ N/A □

Are tissue maintained at defined environmental temperatures? Yes □ No □ N/A □

□ 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 perform?

_____
_____
_____

Does the shipping container include the following information:

- DONATED HUMAN TISSUE Yes □ No □ N/A □

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

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

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 ☐

E1.030 Processing Methods
E1.031 General

Are the processing methods validated to prevent contamination and cross-contamination? Yes ☐ No ☐ N/A ☐

E1.035 Additives

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

E1.050 Tissue Evaluation

For embryo cryopreservation, are there written criteria for the evaluation/assessment of embryo quality? 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-E1.070, where applicable? Yes ☐ No ☐ N/A ☐

E1.067 Freezing Tissue

Is the freezer chamber temperature monitored during each embryo freezing cycle? 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 ☐

Are donors and client depositors giving multiple specimens assigned a secondary code to distinguish between dates of collection? Yes ☐ No ☐ N/A ☐

E1.200 Pooling

How does the facility ensure that pooling is prohibited?

_____

E1.210 Tissue Cross-Contamination

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

_____
_____
_____

□ Review the procedure. Procedure number _____

E1.300 Reagents and Supplies – General

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

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

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

El.310 Stock Rotation
E1.311 Storage

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

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

E1.320 Non-Disposable Supplies

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

_____
_____
_____

E1.400 Tracing of In-Process Tissue

How do you ensure traceability of the tissue?

_____
_____
_____

E1.500 Time Limits for Processing and Preservation Phases

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

Does the SOPM specify a time period appropriate for retention of functional integrity within each exam and/or processing of donor semen specimens? 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 □

E1.700 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

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

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

E4.100 Storage Temperatures

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

E4.120 Frozen and Cryopreserved Tissue

Are reproductive cells stored in either the liquid phase of liquid nitrogen or the vapor phase of liquid nitrogen (if validated)? Yes □ No □ N/A □

Are Oocytes and embryos stored in the liquid phase of liquid nitrogen? Yes □ No □ N/A □

E4.140 Monitoring Storage Temperatures

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

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

_____

_____

_____

Who is responsible for responding to a freezer alert?

_____

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

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

□ Review freezer temperature monitoring procedure. Procedure number _____

E.4.141 Storage Conditions for Commonly Transplanted Human Tissue

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

* Warmest target temperature unless noted to be a range.

** Frozen musculoskeletal: -20^{o}C to – 40^{o}C for storage 6 months or less.

*** Ambient temperature monitoring not required for lyophilized tissue.

E4.150 Emergency Transfers

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

_____
_____
_____

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

_____

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

_____
_____
_____

□ Review emergency transfer procedure. Procedure number _____

E4.200 Storage Devices

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

E4.300 Expiration Date/Storage Period

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

_____
_____
_____

E4.400 Segregation of Cells and Tissue

Does the Medical Director establish procedures for storage of cells and tissues from client depositors or directed donors whose test results are positive or repeatedly reactive? Yes □ No □ N/A □

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

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 ☐

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

How does a contracting retrieval 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 and signed 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

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

F2.100 Tissue Release Based on Tissue Utility

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) — Yes ☐ No ☐ N/A ☐
  - 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 _____

F2.200 Special Circumstances in Release of Reproductive Tissues

(R) Is release of reproductive tissue considered in the special cases listed below:

- *Reproductive Tissues* from *Client Depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg, or any test for sexually transmitted diseases, excluding CMV — Yes □ No □ N/A □
- *Reproductive Tissues* from *Client Depositors* that have not been tested or do not meet current *Standards* — Yes □ No □ N/A□
- *Directed Donors* who have completed all required testing and screening according to *Standards* who had reactive test results on either initial or repeat tests or are determined ineligible according to screening criteria — Yes □ No □ N/A □
- *Directed Donors* who have not completed the 180-day quarantine and re-testing requirement. — Yes □ No □ N/A □

If tissue is released for any of the four circumstances listed above, is the following documentation is required:

- A written description that describes the deviation from *Standards* and what risk(s) potentially exist — Yes □ No □ N/A □
- Medical Director or licensed physician designee review of all relevant information present and approval of the exception — Yes □ No □ N/A □
- A written statement to the attending physician disclosing the deviation(s) from *Standards* and description of potential risks to the recipient — Yes □ No □ N/A □
- A written, signed statement from the attending physician and the recipient indicating that:
  - The attending physician has received the written statement from the reproductive tissue bank and acknowledges the deviation(s) from *Standards* — Yes □ No □ N/A □
  - There has been ample opportunity to discuss the implication with the Medical Director and other medical authorities — Yes □ No □ N/A □
  - The implications have been fully explained to the recipient and she has had ample opportunity to ask questions and consult with experts of her choice — Yes □ No □ N/A □

- The attending physician has obtained documentation of informed consent. Yes □ No □ N/A □

Does the reproductive tissue bank release specimens only after completion of above steps and receipt of formal written approval from the attending physician? Yes □ No □ N/A □

F3.000 TISSUE FAILING REVIEW PROCESS – GENERAL REQUIREMENTS

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 collects tissue? Yes □ No □ N/A □

Are 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

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

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? Yes □ No □ N/A □

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

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

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 □

Are cryocontainers (vials, straws, or ampules) labeled to identify:
- Donor or client depositor identification and batch number and/or other code Yes □ No □ N/A □
- Name, initials, or other code to identify the processing bank 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 ☐
- Statement indicating the reason for determination of ineligibility in the case of tissue from a donor who is ineligible based on screening or testing Yes ☐ No ☐ N/A ☐

G3.220 Package Insert Content

Do package inserts contain appropriate and complete information (Items 1 – 21 in *Standards*? Yes ☐ No ☐ N/A ☐

Does reproductive tissue in the following categories require additional information in the package insert? Yes ☐ No ☐ N/A ☐

- Intended recipient is the sexually intimate partner of the gamete provider Yes ☐ No ☐ N/A ☐
  - Client depositor who is not tested or screened using all parameters required for either a semen or egg donor, including required tests and time limits for donor testing Yes ☐ No ☐ N/A ☐
  - Client depositor who has reactive of positive test results Yes ☐ No ☐ N/A ☐
- Intended recipient is not the sexually intimate partner of either gamete provider Yes ☐ No ☐ N/A ☐
  - Directed donor (semen, oocyte, embryo) with reactive test results Yes ☐ No ☐ N/A ☐
  - Directed (semen, oocyte, embryo) donor determined to be ineligible base on risk factors for or clinical evidence of relevant communicable diseases Yes ☐ No ☐ N/A ☐
  - Directed donors not completing 180-day quarantine and re-testing requirements and/or have incomplete re-testing Yes ☐ No ☐ N/A ☐
- If intended recipient is not the sexually intimate partner of either gamete provider and the tissue is from anonymous or directed embryo donors in cases where the gamete providers were not initially tested as donors but were re-tested following 180-day quarantine Yes ☐ No ☐ N/A ☐
- Reproductive tissue intended for research Yes ☐ No ☐ N/A ☐
  - Client depositor tissue when gamete provider(s) were not tested or screened using all parameters required for either a semen or egg donor, including required tests and time limits for donor testing or donor (anonymous or directed) tissue has not completed 180-day quarantine requirement Yes ☐ No ☐ N/A ☐
  - Donor (anonymous or directed) tissue that has completed 180-day quarantine release requirement Yes ☐ No ☐ N/A ☐
  - Client depositor or donor (anonymous or directed) tissue from gamete providers who had reactive test results or been determined to be ineligible 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 □

AATB STANDARDS SECTION H
DISTRIBUTION AND DISPENSING

N/A □

H1.000 DISTRIBUTION AND DISPENSING

Are there SOPs for:

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

H1.110 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 □

Does the facility distribute client depositor samples? Yes □ No □ N/A □

If yes, how does the facility ensure samples are appropriately released?

_____
_____
_____

H1.120 Semen Distribution Restrictions

How does the facility ensure semen is distributed to appropriate individuals?

_____
_____
_____

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

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

H3.100 Integrity

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

_____
_____
_____

H3.200 Tissue Storage Environment

Is maintenance of 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?

_____
_____
_____

H3.500 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 □

□ Review the final inspection procedure. Procedure number _____

H3.600 Transportation

How is the mode of transportation selected?

_____
_____
_____

H4.000 RETURN OF TISSUE

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?

_____
_____
_____

H5.000 RECALLS—GENERAL

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

□ Review the recall procedure. Procedure number _____

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?

_____
_____
_____

How do you ensure that AATB is notified of recalls within 15 days?

_____
_____
_____

□ 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)

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

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 and state regulations, *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

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 that may affect the safety of tissue, are excluded from retrieval, 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

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 collection 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 retrieval, 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 retrieval, processing, and/or preservation? (airborne particulate cleanliness class)

_____
_____
_____

For collection 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

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 retrieval 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 retrieval, 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?

_____
_____
_____

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

K1.100 Basic Elements

Are the following elements included in the QA Program, where appropriate?

1) Quality Control functions
   a) **Environmental monitoring** (J4.300) Yes ☐ No ☐ N/A ☐
   b) **Equipment and facility inspections** - Performance and documentation in maintenance records/logs of periodic equipment and facility inspections (J5.300 Qualification and Maintenance) Yes ☐ No ☐ N/A ☐
   c) **Supply and reagent review** - Performing acceptability determinations of supplies and reagents (E1.300 Supplies and Reagents) Yes ☐ No ☐ N/A ☐
   d) **Equipment monitoring** - review records for maintenance within specified tolerance limits) (J5.300 Qualification and Maintenance Yes ☐ No ☐ N/A ☐
   e) **In-process control** - inspection and monitoring (C1.100 – Records Management, General, E1.800- Processing and Preservation Records) Yes ☐ No ☐ N/A ☐
   f) Monitoring laboratory performance, if applicable Yes ☐ No ☐ N/A ☐
2) **Validation** (shipping container validation) Yes ☐ No ☐ N/A ☐
   (D5.800 Transportation of Tissue to Processing Center) Yes ☐ No ☐ N/A ☐
3) **Corrective action administration**, (K4.000 Investigation) Yes ☐ No ☐ N/A ☐
4) **QA review** - donor screening, retrieval, 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,
9) 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 ☐
10) **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?

_____

_____

K2.000 QUALITY CONTROL PROGRAM

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?

_____
_____
_____

K4.000 INVESTIGATIONS

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 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 retrieval 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

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 received with corrective action within two weeks of submitting the response to FDA? Yes ☐ No ☐ N/A ☐

AATB STANDARDS SECTION L
TISSUE DISPENSING SERVICES

N/A □

L1.000 TISSUE DISPENSING SERVICES - GENERAL

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?

_____
_____
_____

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

L2.000 STORAGE

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

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 _____

L3.400 Return of Tissue

How do you ensure cryopreserved reproductive tissue is not redistributed that were released to a physician, subsequently not used, and then returned?

_____
_____
_____

L4.000 – RECORDS

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

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

L6.000 RECALLS

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

(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

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

□ 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

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

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

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 within 15 days of recalls? Yes □ No □ N/A □

□ Review the recall procedure. Procedure number _____

M7.000 RECORDS

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 □

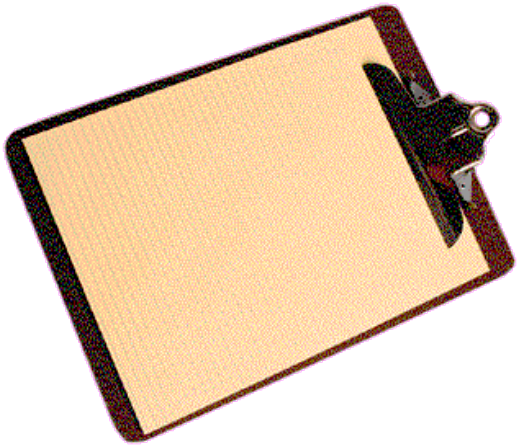
How does the facility ensure all appropriate information is recorded?

_____
_____
_____

M8.000 ADVERSE OUTCOMES

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 CHECKLI ST



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

Bank _____

Donor No. _____

Reviewer _____

Date _____

DONOR RECORD SAMPLING PLAN
INDEX VALUES
(ASSOCIATED AQLS)

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

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

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

DONOR CHART REVIEW
(Revised August 2010)
Review the donor chart for completeness.

Donor Chart Number(s): _____
Type of Review: ☐ Completeness/Accuracy Audit ☐ Tracer Audit
Reviewer/Date: _____

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

Donor Chart Number(s):_____

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

Donor Chart Number(s): _____

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

Donor Chart Number(s): _____

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

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

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

G3.000 LABELING INFORMATION

G3.100 Container Labels

G3.110 Design

Container labels shall be designed to facilitate the use of uniform labeling techniques for each type of tissue.

G3.120 Content

Container labels shall include the *Tissue Identification Number*.

Following information shall be included on 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/or 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, dimethylsulfoxide); and

9) A reference to the *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 definitive identifying information;

3) A label or attached tag ‘‘FOR AUTOLOGOUS USE ONLY’’; and

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.

(R) Cryocontainers (vials, straws or ampules) shall be labeled so as to identify:

1) Donor or *Client Depositor* identification and *Batch* number and/or other code that can be used by the *Reproductive Tissue Bank* to identify the date the specimen was cryopreserved and the stage of development at cryopreservation, where applicable; and

2) Name, initials, or other code that can be used to identify the *Reproductive Tissue Bank* at which the specimen was processed.

Attachment 2

G3.200 Summary of Records and Package Insert

Tissue determined to be suitable and released for transplantation shall be accompanied by a *Summary of Records* and *Package Insert.* A *Summary of Records* is not required if a donor suitability determination is not required (i.e., autologous tissue and certain types of reproductive tissue).

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 HTLV 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.

(R) A statement noting the reason for the determination of ineligibility in the case of a cell or tissue from a donor who is ineligible based on screening and/or testing.

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);

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

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

14) Instructions for preparation of tissue for transplantation;

15) Expiration time of tissue following reconstitution;

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

17) Recommended storage conditions and *Tolerance Limits*;

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

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

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

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

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

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

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

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

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

4) Date of dissection or *Preservation*;

5) Tissue *Warm Ischemic Time*;

6) Tissue *Cold Ischemic Time*;

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

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

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

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

11) Instructions for preparation of tissue for use.

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

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

(R) See F2.200 Special Circumstances in Release of Reproductive Tissues for additional requirements regarding release of tissue from *Directed Donors* with reactive test results, incomplete 180-day quarantine, or who are ineligible based on screening, as well as *Client Depositors* with reactive test results or incomplete test results.

Reproductive Tissue in the following categories require additional information in *Package Inserts* as listed below:

1) If the intended recipient is the sexually intimate partner of the gamete provider(s):

Note: a *Summary of Records* is not required for this category.

a) For all reproductive tissue, include the statement: ‘‘For use by Sexually Intimate Partner Only.’’

b) For all reproductive *Client Depositors* who were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, include the statements:

1. ‘‘Not evaluated for Infectious Substances’’; and

2. ‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’

c) For all reproductive *Client Depositors* who have reactive or positive test results:

1. Biohazard symbol; and

2. ‘‘WARNING: Reactive test results for (insert name of test).’’

2) If the intended recipient is NOT the sexually intimate partner of either gamete provider, the following labeling is required in addition to a *Summary of Records*:

a) Directed donors (semen, oocyte, and/or embryo) with reactive test results:

1. Biohazard symbol;

2. ‘‘WARNING: Reactive test results for (insert name of test)’’; and

3. ‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’

b) Directed (semen, oocyte, and/or embryo) donors determined to be ineligible based upon risk factors for or clinical evidence of relevant communicable disease agents or diseases, including the physical examination:

1. Biohazard symbol; and

2. ‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’

c) Directed donors not completing 180-day quarantine and re-testing requirements and/or have incomplete re-testing:

1. ‘‘Not evaluated for Infectious Substances’’; and

2. ‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’

3) If the intended recipient is NOT the sexually intimate partner of either gamete provider, and the tissue is from anonymous or directed embryo donors in cases where the gamete provider(s) was (were) not initially tested as donors, but were re-tested following 180-day quarantine:

(Note: A *Summary of Records* is not required for this category, however, a summary of the test results must be included.)

a) ‘‘Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently.’’

4) Reproductive Tissue intended for Research:

a) *Client Depositor* reproductive tissue when gamete provider(s) were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, or donor (anonymous or directed) tissue has not completed 180-day quarantine release requirement:

1. ‘‘For Non-Clinical Use Only’’; and

2. ‘‘Not evaluated for Infectious Substances.’’

b) Donor (anonymous or directed) tissue that has completed 180-day quarantine release requirement:

1. ‘‘For Non-Clinical Use Only.’’

c) Client Depositor or donor (anonymous or directed) tissue from gamete provider(s) who had reactive test results OR have been determined to be ineligible:

1. Biohazard label;

2. ‘‘For Non-Clinical Use Only’’; and

3. If applicable, ‘‘WARNING: Reactive test results for (insert name of test).’’