



Guidance Document

Recovery Partner Audit Tool

[No. 6, version 1, September 1, 2011]

To be implemented by: January 1, 2012

American Association of Tissue Banks' (AATB) guidance documents, including this one, do not establish legally enforceable responsibilities. Instead, these guidelines describe the AATB's current thinking on this topic. They are intended solely for the use of AATB accredited tissue banks in conjunction with the AATB's Standards for Tissue Banking. They should be viewed only as recommendations, unless specific AATB Standards or regulatory or statutory requirements are cited. The use of the word "should" in these guidance documents means that something is suggested or recommended, but not required. As with other AATB guidance documents, the recommendations included in this document do not represent the sole approach. Alternative approaches can be used.

***American Association of Tissue Banks
1320 Old Chain Bridge Road
Suite 450
McLean, Virginia 22101***

Additional copies of this *Guidance Document* are available from the AATB office. In addition, comments on this document may be submitted at any time to the AATB. The Association will review any comments received and revise the *Guidance Document* as appropriate. All requests and comments should be addressed to:

American Association of Tissue Banks
Suite 450
1320 Old Chain Bridge Road
McLean, Virginia 22101
www.aatb.org

For questions on the content of the document, please contact the AATB at:

(703) 827-9582 or (703) 356-2198 (Fax)

Mention of specific products or equipment in this AATB publication does not represent an endorsement of such products or equipment by the AATB, nor does it necessarily indicate a preference for those products or equipment over other similar competitive products or equipment. Any forms and/or procedures in this document are examples. The AATB does not imply or guarantee that the materials meet federal, state, or other applicable requirements. It is incumbent on the reader who intends to use any information, forms, policies, or procedures contained in this publication to evaluate such materials for use in light of particular circumstances associated with his or her facility.

Efforts are made to have publications of the AATB consistent concerning acceptable practices. However, for several reasons, they may not be. As new developments in the practice of tissue banking occur, changes may be recommended to the *Standards for Tissue Banking*. It is not possible, however, to revise each publication at the time such a change is adopted. Thus, it is essential that the most recent edition of the *Standards* be consulted as a reference regarding current acceptable practices. The publication of this guidance document does not constitute an endorsement by the AATB of these recommendations as the only acceptable practice. The AATB expressly disclaims any liability arising from any inaccuracy or misstatement herein.

The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to this project.

Murray Anderson	Scott Brubaker	Rochelle Maney
Karen Baer	Jeanee Conforte	Allyson May
Allison Bagley	Mary Beth Fisk	Sue Monte
Cheryl Bagwell	Keri Hacker	Debbie Butler Newman (editor)
Michael Bauer	Angela Kiracofe	Helen Pierce
Sue Brewster	Paul Kostiak	James SaFranko
		Lisa Upshaw

TABLE OF CONTENTS

I.	Introduction	4	
	A.	Purpose	5
	B.	Definitions	6
	C.	Materials	7
	D.	Safety	7
II.	Indication for Use	8	
III.	Audit Activities	9	
	A.	Paper Audits	9
	B.	On-Site Audits	9
	C.	Pre-Audit Activities	10
	D.	Opening Meeting for On-Site Audits	12
	E.	Conducting the Audit	12
	F.	Post-Audit Activities	13
IV.	References	14	
V.	Suggested Objective Evidence	15	
VI.	Donor Record Sampling Plan	22	
VII.	Tracer Audit Form	23	
VIII.	Recovery Partner Audit Tool	26	

AATB GUIDANCE DOCUMENT RECOVERY PARTNER AUDIT TOOL

I. INTRODUCTION

Within AATB's *Standards for Tissue Banking*, there is a requirement related to auditing organizations performing activities for accredited tissue banks. Standard B1.521 requires that "Before an entity performs any activity under contract, agreement or other arrangement, 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, at least biennially, that the activities or service(s) has/have been performed in *compliance* with these *Standards*, federal regulations, and applicable state or local laws. This requirement does not apply to any other AATB-accredited entity. When applicable, this must be documented on a form provided by, or pre-approved by, the AATB Director of Accreditation (refer to the AATB Accreditation Policies). The verification of activities or services performed by others shall be documented (e.g. a *paper audit*, on-site *audit*, on-site inspections, etc.). Regardless of whether the facility performing activities or services for others is accredited, it is the responsibility of the tissue bank receiving those activities/services to periodically verify that procedures related to the activities/services performed are in *compliance* with these *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract. The inspection/audit plan, policies, and procedures shall be specified in the SOPM." This means that though a formal *audit* is not required of AATB-accredited tissue banks every two years, there must be periodic verification that these entities comply with *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract. This may be accomplished by completing a *paper audit* that may also include review of licensures, accreditation certificates, certificates of conformance, etc. This verification must be documented. The standard also describes expectations for documenting these verification activities: "Documentation that an audit/inspection specific for activities or services performed shall be maintained by the tissue bank. Such documentation shall itemize all operational systems that were verified to determine *compliance* with these *Standards*, federal regulations, applicable state or local laws, and the agreement/contract. This itemization of the systems reviewed shall be provided to AATB on-site inspectors upon request."

"If, during the course of this contract, agreement, or other arrangement, information suggests that the entity may no longer be in *compliance* with such requirements, the accredited bank must take steps to ensure *compliance*. If it is determined that the entity will not comply, the contract, agreement, or other arrangement must be terminated."

AATB Bulletin No. 06-56, Special Oversight Task Force Initial Report and Recommendations, indicated, "AATB-accredited tissue banks bear the ultimate responsibility for ensuring that their recovery agents follow AATB *Standards*, including standard B1.520 On-Site Audits." Accredited tissue banks must perform *audits* (as required) to confirm *compliance* with contracts and AATB *Standards*. The Bulletin indicated that AATB takes this seriously, and that AATB inspectors may inspect recovery partners as part of the AATB *inspection* process, even if the recovery partner is not an AATB-accredited tissue bank.

To assist AATB-accredited tissue banks to completely and properly *audit* non-accredited recovery partners, an AATB task force, composed of AATB members, developed a “Recovery Partner Audit Tool” and this corresponding Guidance Document as a useful resource. Tissue banks auditing non-AATB-accredited recovery partners must use the Recovery Partner Audit Tool or submit their own tool to the Director of Accreditation at the AATB Executive Office for evaluation. If the tool is deemed to be comparable to the Recovery Partner Audit Tool, you will be able to use that tool.

This tool is not intended for conducting *audits* of the following:

- Establishments that are only obtaining authorization/consents and/or donor risk assessments on behalf of the establishment that distributes tissue (i.e., eye bank, OPO)
- Processing establishments
- Banks that only store and/or distribute tissue
- Non-Transplant Anatomical Donation Organizations (NADO)
- Sterilization facilities (i.e., hospital, sterilization contractor)
- Reference/testing laboratories
- Materials suppliers.

For *audits* of the above establishments (except authorization/consent, processing, storage and/or distribution establishments and NADOs), each establishment should develop a specific audit tool that includes *Standards* requirements that apply to that function. The Self-assessment Tool/Audit Report (STAR) must be used to *audit* the authorization/consent, processing and tissue storage and/or distribution establishments and NADOs unless a substitute document is submitted to AATB’s APM for approval. The STAR is available on the AATB website (aatb.org) under Accreditation and the Accreditation Documents.

A. Purpose:

The purpose of this Guidance Document is to describe how to properly complete the Recovery Partner Audit Tool. The information contained on these pages and in the Audit Tool may be used as an aid to determine recovery partner compliance.

The Recovery Partner Audit Tool, or other approved audit tool, must be completed before a recovery partner that is not AATB-accredited performs any activity under contract/agreement. The tissue bank must ensure that the recovery partner will comply with applicable AATB standards, federal regulations, and applicable state or local laws.

B. Definitions:

(Words that appear in the Definitions are *italicized* in this document.)

Audit - A documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors to evaluate adherence to the written SOPM, *Standards*, and/or federal, state and/or local laws. An audit may be an on-site or paper review.

Auditee – An organization or facility whose processes are being assessed for *compliance* to *Standards*, applicable federal, state, and/or local laws. May be an on-site audit/inspection or paper review.

Auditor – One who is assessing an organization or facility's processes for *compliance* with *Standards*, applicable federal, state, and/or local laws.

Compliance/Conformance – Fulfillment of a requirement as per regulations, state and local laws, and/or *Standards*

Designated Representative – The main contact person at the facility to be audited.

Desktop pre-audit review – Review of documentation to become familiar with the *auditee's* processes and to identify potential areas of focus for an on-site *audit*.

Inspection - An on-site documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors to evaluate adherence to the written SOPM, *Standards*, and/or federal, state and/or local laws. Equivalent to the term "on-site audit."

Nonconformity – A finding that identifies a non-fulfillment of an accreditation requirement, policy, process, or procedure, which may have an impact on the safety or utility of tissue, or the safety of a tissue bank employee, that is more than a single occurrence or sporadic event and that can be supported by objective evidence.

Observation - May be a positive comment or reflection of an activity, or it may be a negative comment or remark that identifies a non-fulfillment of an accreditation requirement, policy, process, or procedure, which is usually a single or sporadic occurrence (isolated incident) rather than a systemic event, that can be supported by objective evidence.

Paper Audit - Review of documentation (records, logs, procedures, policies, etc.) to verify *compliance* with AATB *Standards*, applicable federal, state, and/or local laws. Conducted in lieu of an on-site *audit*, *paper audits* may be performed either by mail or electronically. This type of *audit* relies heavily on the *auditee's* ability to provide sufficient documentation in response to questions asked by the *auditor*.

Recovery Partner - An entity that obtains donated human tissue and provides that tissue to another entity that is not under the same management or direct supervision of the same corporate entity.

Satellite Facility – An establishment in a physically separate location where any activities occur that contribute to recovery, transport, processing, storage, packaging, labeling or distribution of human tissue under the management or direct supervision of the same corporate entity or its employee(s).

Standards – Current AATB *Standards for Tissue Banking*.

Tracer Audit – Review of a targeted process from start to finish, including evaluation of activities associated with that event. (e.g., audit of a donor chart, from donor referral to transportation to processing center, and review of all items associated with the donor, including reagents, supplies, instruments, storage of tissue, logs, etc.). The audit can be performed forwards or backwards.

C. Materials:

The following items and materials will be used:

- Indelible ink pen (black preferred)
- AATB Recovery Partner Audit Tool
- *Standards for Tissue Banking* (current edition)
- Applicable federal, state, and/or local laws and/or regulations.

D. Safety:

Auditors should follow established bloodborne pathogen standards, applicable Occupational Safety and Health Administration (OSHA) regulations, guidelines established by the CDC, applicable federal, state, and/or local laws and/or regulations, and *auditee* requirements.

II. INDICATIONS FOR USE

Each accredited organization that processes tissue shall establish an audit schedule of contract recovery partners. In accordance with standard B1.521 the *audit* of banks that are not AATB-accredited must occur, biennially (every two years) at a minimum. Regardless of whether the facility performing activities or services for others is accredited, it is the responsibility of the tissue bank receiving those activities/services to periodically verify that procedures related to the activities/services performed are in compliance with these *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract.

The Recovery Partner Audit Tool (or another pre-approved audit tool) must be used for conducting on-site *audits* of recovery, or potential recovery, partners that are not accredited by AATB, and may be used for recovery partners that are accredited by AATB. The STAR or a form approved by AATB, may also be used to *audit* AATB-accredited tissue banks. Those establishments who conduct *paper audits* may also use the Recovery Partner Audit Tool by requiring the recovery partner to complete the tool and submit the completed document to the *auditor* for review.

Since this Recovery Partner Audit Tool is a new form, if a bank is already using its own pre-approved form to audit recovery partners that are not AATB accredited and wishes to continue using its own audit tool, the audit tool must be re-submitted, to AATB for approval, even if the audit tool was previously approved by AATB. Submission of a non-standard audit tool for approval must include any associated SOP(s). After approval is granted for the audit tool, it must be submitted to AATB for review if major revisions occur.

The Recovery Partner Audit Tool is organized by function rather than by standard number; therefore, standards from several sections of the *Standards* may be in one section of the audit tool.

III. AUDIT ACTIVITIES

According to AATB standard B1.521, “The verification of activities or services performed by others shall be documented (e.g., a *paper audit*, on-site *audit*, on-site *inspection*, etc.)” The purpose of paper and on-site audits are to provide documented verification of compliance with *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract.

A. Paper Audits:

Paper audits are conducted either by mail or electronically. This type of auditing relies heavily on the *auditee’s* ability to provide sufficient documentation in response to questions asked by the *auditor*. Information requests may appear in the form of a questionnaire, checklist, or request for specific pieces of documentation. Conducting this type of *audit* has its advantages as well as disadvantages. Advantages include simultaneous assessment of multiple sites while minimizing the drain on critical resources. A disadvantage is that if the request is not specific, the information provided by the *auditee* may not fully address the request.

If a *paper audit* is conducted, the name(s) of the individual(s) responsible for completing the audit tool must be included on the completed tool.

B. On-Site Audits:

On-site *audits* are conducted at the recovery partner location, which can be at the main site or at a *satellite*, or both locations. The *audit* may also include a visit to any recovery suites at other locations and may include auditing a recovery if one is taking place wherever the recovery occurs. This form of auditing allows the *auditor* to observe the daily operations of the facility and provides the opportunity to actively gather information and documentation to determine *compliance* or non-compliance. It also allows the *auditee* the chance to immediately address a *nonconformity and/or observation* when it is discovered, which may benefit both parties by permitting open dialogue while the *auditors* are still present.

Auditing can be divided into three distinct activities: *pre-audit*, *audit*, and *post-audit*. Within this section, the purpose and principle for all three will be discussed to provide the Recovery Partner Audit Tool user additional information on how to apply it.

C. Pre-Audit Activities:

Initially, the *auditor* should identify the purpose and scope for the *audit*. There may be many reasons to conduct an *audit*, for example: there has been a drastic increase in the number of allografts not meeting specifications (e.g., increased rates of positive pre-processing culture results, torn packaging and labeling errors). Or, the *audit* may be routine. Upon defining the purpose of the *audit*, the scope can be shaped.

The scope should be as precise as possible to prevent ambiguity (specific to minimize the possibility of misinterpretation). Formulation of the scope should include what recovery-related functions or processes will be assessed. For example, the *audit* may pertain only to soft tissue recovery processes or the donor eligibility process, or to all recovery functions. The audit may also be limited to specific functions such as the QA program, training, materials management, etc. Defining the scope early will provide a point of focus during the *audit* (or when the tool is being completed by the recovery partner). Once the purpose and scope are developed, contact the recovery partner to be audited.

For *paper audits*, the Recovery Partner Audit Tool can be utilized in two different ways.

- The tool may be broken up into smaller portions to be completed by the *recovery partner* over a period of time.
 - Organizing the recovery audit tool into smaller and more manageable pieces is ideal (those of you who have responded to lengthy questionnaires can appreciate this).
- The entire tool may be forwarded to the recovery partner for completion by a specified date.
 - Requiring the *auditee* to address all the elements identified in the recovery audit tool at one time, may be challenging.
 - It is advisable that this approach only be used when qualifying a new recovery partner that is not accredited by the AATB or if there have been severe breaches in protocol resulting in FDA recall notification.

Once the method of paper auditing is decided upon, forward the document to the *designated representative*. The *auditor* should include in the notification:

- Types of documentation required to demonstrate *compliance* (see documents to request for desktop audit listed below).
 - Stress that responding to a question as only “satisfactory” is insufficient.
 - There must be documentation provided to support the response.
 - Whether it is paper or electronic, it is imperative and the responsibility of the *auditee* to provide evidence of *compliance*.
- Due date for submission of Recovery Partner *Audit Tool*.
 - For full Recovery Partner Audit Tool, allow at least 30 days. (60 days is customary).
 - For partial Recovery Partner Audit Tool, allow at least two weeks.

- contact reduces the possibility of confusion and provides consistency when responding to questions asked by the *auditee*.

For on-site audits, identify a mutually agreeable date for the *audit* and request documents be forwarded to allow sufficient time for your review prior to arriving on-site. Send a confirmation letter to the *auditee* that includes the *audit* date(s), time the *auditor* will arrive, duration of the *audit*, scope of the *audit*, and the *audit* plan.

When the *pre-audit* documents have been obtained, conduct a *desktop pre-audit review*. A *desktop pre-audit review* permits the *auditor* to become familiar with the *auditee*'s program. Reviewing the program before the on-site visit allows the *auditor* to get an idea as to how the facility operates and presents an opportunity to identify which elements of the AATB *Standards* and ten core CGTPs are addressed within their program. In addition, it allows the *auditor* an opportunity to identify items that appear to be vague and/or unclear and will require further follow up at the site.

Documents to request for the *desktop pre-audit review* may include, but are not limited to:

- Operations information, including:
 - Quality plan or policy.
 - Organizational mission statement.
 - Outline of current activities - Provides an overview of which activities occur at the site where the *audit* is to be performed.
- Current organizational chart(s) - To understand operational layout and identify where responsibilities are assigned.
- Master list of documents.
 - Identification of policies and procedures that support items listed in the Recovery Partner Audit Tool.
- List or schedule of all internal and external *inspections*/assessments for the past two years (or since the date of your last *audit*, whichever applies).
- List of supplier/contract services.

Some other documents or reports that may be desirable to review during a *desktop pre-audit review* include, but are not limited to:

- The written agreement/contract between the *auditee* and the entity responsible for the *audit* that defines partner/service provider expectations and responsibilities.
- All complaints, errors, and/or accidents related to this recovery partner that have occurred since the last *audit*.
- Review of trend analysis for tissue recovery activities performed by this recovery partner that are to be assessed by the *auditor*.

Upon completion of the *desktop pre-audit review* and using the Recovery Partner Audit Tool as a reference, generate a checklist outlining the areas to concentrate on or that need clarification during the *audit*.

D. Opening Meeting for On-site Audits:

Once on-site, conduct an opening meeting. During the course of the opening meeting, the following should be communicated:

- *Audit* purpose and scope.
 - If the *audit* is not routine, explain what led to the *audit* and, if necessary, provide specific examples.
- How *nonconformities* and/or *observations* are classified, defining the differences between a ‘*nonconformity*’ and an ‘*observation*.’
- Identify and establish an official communication link. Clarify who will be the *designated representative* and what role the *designated representative* will play.
- Verify that necessary resources, personnel, and facilities will be available for the *audit*. Stress that the *audit* will be minimally disruptive to normal operations.
- Reinforce that all *nonconformities*, *observations*, documentation and *audit results* will be kept confidential.
- Identify a possible date and time for the closing meeting.
 - This allows for flexibility in scheduling.
- Indicate when the formal Audit Report will be completed and forwarded to the *designated representative*.

E. Conducting the Audit:

Auditing is the process of verifying *compliance* with requirements identified within the Recovery Partner Audit Tool. Obtain objective evidence to establish whether current processes and practices are in *compliance* or non-compliance with the *Standards*. Suggested objective evidence/guidance for each section of the *audit* tool is provided in this Guidance Document. These objective evidence/guidance items are just suggested; you may develop your own objective evidence items. Objective evidence includes:

- Direct observation - Observing activities and practices for *compliance*.
- Interviews - Speaking with personnel to gain further understanding of processes.
- Review of relevant records and/or documents.

When *nonconformities* and/or *observations* are identified, gather and provide sufficient details to allow the *auditee* to reproduce and investigate the event/issue and to initiate corrective action. When describing *nonconformities* and/or *observations* utilize accurate and specific details including:

- Using unique identifiers or lot numbers for donor tissue, reagents, or equipment.
- Referencing the specific Standard Operating Procedure for identified breaches in protocol or non-compliant procedures.
- Identifying staff involved in direct observation of the *nonconformity* and/or *observation*.
 - Staff should be addressed by title, never use names.
 - If there is more than one person with the same title and it is important for proper identification of the *nonconformity* and/or *observation*, the title and their initials may be used.

- Seeking additional evidence by asking questions and reviewing additional documentation, if needed, to support *nonconformities* and/or *observations*.

For *paper audits*, upon receipt of the completed *audit* tool, review all responses against supporting documentation. If inconsistencies or gaps are identified, contact the *designated representative* and request more information.

For on-site audits, notify the *designated representative* when *nonconformities* and/or *observations* are identified. This allows the *auditee* an opportunity to address the *nonconformity* and/or *observation*. In order to keep disruptions to a minimum, you may wish to conduct a meeting at the end of each day to review issues that are identified as *observations*. If corrective action is completed during the course of the *audit*, include it in the audit summary for presentation at the end of the *audit* and inclusion in the Audit Report.

Classify the issue as a ‘*nonconformity*’ or an ‘*observation*’ (as defined in the Definitions) or use a similar classification scheme.

F. Post-Audit Activities:

At the conclusion of the *audit*, generate an audit summary for presentation. The summary will serve four purposes:

- Presents well documented logical explanations of the potential *nonconformities and/or observations* found during the *audit*.
- Provides a platform to ensure that the *auditee* clearly understands the outcome of the *audit*.
- Provides the *auditee* an opportunity to state the bank's case when differences of opinion surface for *nonconformities and/or observations* identified during the *audit*.
- Offers an opportunity for the *auditors* to solicit corrective actions from the *auditee*.

Remember to provide positive feedback on outstanding practices you observed.

State when the final Audit Report will be completed and identify who will receive copies of the Audit Report in accordance with the *auditee*'s protocol. Specify your expectation for a response date to the Audit Report (it is common to request a response within 60 days). The *auditee* must be informed that the *audit* will remain in an open, unresolved status, until a sufficient response is received to each *nonconformity and/or observation*.

When you decide the *audit* can be closed, produce a final Audit Report, send it to the *auditee*, and maintain a copy for your file.

IV. REFERENCES

AATB *Standards for Tissue Banking*, current edition, McLean, VA.

AATB *Bulletin* No. 06-56 August 15, 2006

AATB *Bulletin* No. 07-53 August 13, 2007

(<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm095440.htm>

<http://www.fda.gov/cber/products/testkits.htm>)

Quality Audits for Improved Performance, by Dennis Arter (current edition), published by the American Society for Quality.

ISO 19011:2002 Guidelines on Quality and/or Environmental Management Systems Auditing

V. SUGGESTED OBJECTIVE EVIDENCE/GUIDANCE

Below are suggested objective evidence and guidance items that may be utilized to help determine compliance with AATB *Standards for Tissue Banking*. These are only *suggested*; you are not required to use these items, you may develop your own objective evidence items.

1

Registration, Licensures, and Accreditations

Suggested Objective Evidence/Guidance:

1. Obtain copies of certifications, registrations and licensures for audit files. (A1.000)
2. Review certificates and confirm certificates/registrations are present and current for the recovery agency, any satellite facilities, and any laboratories it does business with. (A1.000)
3. Review to see that the facility has current copies of the contract laboratories' certifications/licensures. (B1.600)
4. Request that any updates to these documents be forwarded to keep the files current. (A1.000)
5. Review any Federal, State and/or local inspectional reports. (A1.000)
6. If satellite facilities are present, review what activities are performed at the satellite facilities. (B1.400)
7. Review evidence that audits are performed of satellite facilities. (B1.400)
8. Review how the SOPs are communicated to the satellite facilities to ensure that the most current revisions are available. (B1.400)

2

General Information

Suggested Objective Evidence/Guidance:

1. Review the mission statement; does it define the agency's purpose? (B1.100)
2. Obtain copy of organizational chart for the audit file. (B2.122) and review the organizational chart; is the purpose of the organization clearly documented and is leadership adequate? (B2.122)
3. If there are satellite facilities, are they shown on the organizational chart? (B1.100)
4. Describe how the Director ensures compliance with all applicable federal, state, and/or local laws and regulations and AATB Standards. (B2.121)
5. Obtain copy of Medical Director's license to practice medicine. (B2.210)
6. Review how documentation of medical/scientific support is maintained. (B1.300)
7. Review applicable contract; is it complete and accurate and does it contain all required elements? (B1.510)
8. Determine how the tissue bank ensures establishments that perform manufacturing functions on its behalf comply with AATB Standards. (B1.500)
9. Determine how the facility ensures that the contract laboratory is operating in compliance with applicable rules and regulations. (B1.600)

3

Quality Program - General

Suggested Objective Evidence/Guidance:

1. Review the Quality Assurance Program; does it address all QA requirements? (B2.420) (K1.100)
2. Verify that in-process control records are complete, accurate, and performed at specified intervals. (K1.100)
3. Verify that validation records are complete, accurate, and appear to contain data to support that the process is effective and repeatable. Includes shipping methods and containers. K1.200)
4. Review equipment qualification records to determine if equipment is capable of producing valid results. (K1.100)

4

Standard Operating Procedures Manual (SOPM)

Suggested Objective Evidence/Guidance:

1. Review the SOPM. Are all procedures present, current, and followed as written, including information sharing procedures? (J1.300)
2. Verify that procedures are in place to prevent mix-ups. (K1.100)
3. Review procedures for acceptable age criteria requirements. (D4.400)
4. Review package labeling meets SOPs. (D5.800)
5. Review the methods used to approve, maintain, and control labels and labeling. (K1.100)
6. Where does the recovery partner have a mechanism to share records as required and is this stipulated in agreements? (D4.500)
7. Review procedures for information sharing requirements. How does the tissue bank ensure information is shared timely? (D4.500)
8. Review the SOPM. Are there procedures for ensuring that all instruments, solutions, and supplies used for recovery are sterile? (D6.000)
9. Review the tissue recovery procedures. Are the procedures clear and do they contain all required elements? (D5.000)
10. Review the SOPM review documents. Do appropriate personnel review relevant SOPs?
11. Do the Director and Medical Director review and approve specified SOPs as required?
12. Review the medical related procedures for evidence of Medical Director involvement. (B2.221)
13. Assess the availability of pertinent procedures at the work place. (J1.700)
14. Review the archive system for storing obsolete procedures. (J1.900)

5

Donor Records

Suggested Objective Evidence/Guidance:

1. Review selected donor records for accuracy and completeness. At a minimum, use the attached Donor Record Sampling Plan to determine the number of records to review. (C2.000)
2. Verify one or more facts on each of the selected representative records (e.g. cause of death, donor age, primary physician's telephone number, etc.). (C2.000)

Possible resources for verifying donor record information include:

- ✓ 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

(Refer to donor chart checklist at the end of this report).

6

Quality Program - Laboratory Qualification and Infectious Disease Testing

Suggested Objective Evidence/Guidance:

1. Review documentation for contracted laboratory services; is name and address of the lab maintained with inclusive dates of the contract period? (B1.600)
2. Where are contract laboratory services documented? (B1.600)
3. Obtain a copy of any license or certification associated with the lab (e.g. CLIA). Are certificates current?(K2.000)
4. Review infectious disease testing procedures for compliance with Standards. (D4.353)
5. Review selected donor records to determine that all required infectious disease tests have been performed. Is there evidence that appropriate parties have been notified of positive results? (D4.354, D4.356)
6. If applicable, are specific FDA-approved infectious disease test kits used? (See AATB Bulletin 07-53, 08/13/07). (B1.600)
7. Review the procedure for archiving serum samples. Are samples archived according to procedures? (D4.357)
8. Verify that information sharing is accurate and performed in a timely manner, and is part of donor record. (K1.100)
9. Review the procedure for collecting blood samples for serology testing. Is the procedure adequate? Interview staff, do they know the procedure? (D4.351)

Suggested Objective Evidence/Guidance:**Audits:**

1. Review the internal audit schedule and look for annual completion dates. (K5.000)
2. Review for evidence that an internal audit has been performed. (K5.000)
3. If audits are performed by an internal or external source, review the audit schedule to verify that audits are performed at appropriate intervals. (K1.100)

CAPA:

1. Review the facility policy regarding investigating nonconformities and/or observations and interview the Director or designee regarding nonconformities and/or observations. (K4.000)
2. Interview staff regarding nonconformities and/or observations, inspect data including corrective actions and effectiveness checks. (K4.000)
3. Review the reportable events log and corrective actions including any effectiveness checks that were performed. (K4.000)
4. Review corrective actions. (K4.000)
5. Review the files for complaints and adverse outcomes. Are these documented, followed up on, and corrected? (K4.000, K4.200, K4.300)
6. Review records associated with errors, accidents, adverse events, and complaints for completeness, accuracy, timely conclusion, and timely implementation of corrective action. (K1.100)
7. Review the procedure for customer complaints and inspect data and communications regarding complaints. Interview the Director or designee for current practice and ensure that if complaints are medical in nature there is a policy for notifying the Medical Director. (K4.200)
8. Review the policy and "reportable events" log regarding corrective action for positive cultures. Interview the Director or designee regarding the procedure. (K4.000)
9. Review the policy for processor notification regarding unsuitable tissue. Review donor charts and documentation of processor notification. (K4.310)

Quality Control:

1. Review quality control procedures associated with key program elements and determine if records are complete, accurate, and performed in a timely manner. (K2.000)

Computers:

1. Review the facility policy regarding computer security. Interview the Director or designee to determine who has access to records. (K6.400)
2. Interview staff to ensure that limitations are in place and changes are made only by those with authority to make changes. (K6.100)
3. Review the policy regarding backup files and interview the Director or designee. (K6.300)

8

Materials Management

Suggested Objective Evidence/Guidance:

1. Verify that incoming supplies and reagents are inspected and/or tested before release for use. [Examine inventory for proper storage conditions and proper stock rotation (FIFO)] (K1.100)
2. Is there a procedure for storing reagents according to manufacturers' instructions? (D6.000)
3. Verify that reagents and supplies are within expiration dating. (E1.310 and K1.200)
4. Review the supply storage area(s). Are instruments and supplies stored appropriately? (D6.000)

9

Equipment

Suggested Objective Evidence/Guidance:

1. Review maintenance and cleaning records for completeness, accuracy, and specified intervals. (J5.300)
2. Verify equipment is properly identified with calibration information. (J5.300)
3. Review calibration records. Are records complete, accurate, and is calibration performed at specified intervals? (J5.300)
4. Review storage units for appropriate labels and temperature monitoring. (J5.500)
5. If sterile instruments are received from an outside source, determine how the tissue bank ensures that the instruments are sterile. (D6.000, B1.521)
6. Verify that sterile instruments are identified with an expiration date, if applicable. (K1.200, 1271.210)
7. Verify defective equipment/instruments are removed from service or identified as "Out of Service" until repaired. (J5.300)
8. Review equipment use records to determine that equipment/instruments are inspected routinely before use. (1271.195)

10

Facilities

Suggested Objective Evidence/Guidance:

1. Tour the facility and observe its organization, cleanliness, lighting, ventilation, and plumbing. (J4.100, J4.200, J4.210)
2. Are these adequate for the activities being performed? (J4.100, J4.200, J4.210)
3. Does the facility have designated space for activities that require designated space? (J4.200)
4. Review facility cleaning documentation for completeness, accuracy, and intervals being met. (J4.210)
5. Is the facility secure? (J4.400)
6. Review staff access privileges do they meet requirements defined in the procedure? (J4.400)
7. If possible, observe cleaning of the recovery site and observe a tissue recovery. (D5.510)

11 *Recovery Process*

Suggested Objective Evidence/Guidance:

1. Review the procedure for assigning unique donor identification. Could duplicate numbers be assigned? (D5.200)

Authorization/Consent:

- 1. Review the authorization/consent document. (D2.000)*
- 2. Verify that the authorization/consent form contains all required elements. (D2.000)*
- 3. Review several completed authorization/consent forms. Do the types of tissues to be recovered correspond with the tissues that were recovered? Are the authorization/consent documents complete and accurate? (D2.400)*
- 4. Review a few randomly selected recordings and/or verify selected facts from the witnessed (if required) authorization/consent forms or transcriptions. (D2.300)*
- 5. Review donor charts or other files for evidence of implementation and documentation of services provided to donor families. This may include such things as:*
 - Written communications regarding potential uses of tissue; (Appendix III)*
 - Bereavement support; (D2.600)*
 - Providing a copy of the Authorization/ Consent Document; (Guidance Document 4)*
 - Guidance on how to contact the tissue bank with questions regarding donation. (Guidance Document 4)*
- 6. Review the policy regarding monetary compensation. Is the policy clear? (D3.000)*
- 7. Review the physical assessment form; does it comply with AATB Standards? (D4.210, Guidance Document 1)*

Physical Assessment:

- 1. Review the physical assessment procedure; is it adequate? (J1.200)*
(Specific documentation methods (a form) and a standard operating procedure for performing a tissue donor Physical Assessment can be found by referencing AATB Guidance Document # 1. This method, or an equivalent method, must be implemented; the Physical Assessment Form is required). Review the FDA Guidance for Industry Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

Donor Risk Assessment:

- 1. Review the medical/social history questionnaire; does it contain all items listed in Appendix II of the AATB Standards for Tissue Banking? (You may use Appendix II in the AATB Standards for Tissue Banking to document whether the medical/social history questionnaire contains all required elements and applicable standards in Section D (D4.100 General, (C) and (V), D4.220 – Donor Risk Assessment, D4.320 – Miscellaneous Adverse Conditions (including MS), and D4.340)*

Miscellaneous:

- 1. Review the plasma dilution procedures and algorithm. Is the algorithm correct? (D4.352)*
- 2. Review selected recovery records for accuracy and completeness. (D5.600)*
- 3. Observe an individual gowning for a tissue recovery. (D5.510)*
- 4. Verify that there are written time limits for recovery that adhere to standards. (D5.400)*

Continued...

11 (Continued)

Recovery Process

Suggested Objective Evidence/Guidance:

Recovery:

1. *If a recovery cannot be observed, review all appropriate procedures and interview staff members to determine their knowledge of procedures and proper technique, including:*
 - *Confirming authorization/consent was obtained (D5.110)*
 - *Verifying the identity of the donor (D5.120)*
 - *Ensuring the recovery site is cleaned properly. (D5.510)*

Post-Recovery:

1. *Review post-recovery packaging procedures. (D5.700)*
2. *If possible, observe post-recovery packaging. Is it performed according to Standards and the SOP? (D5.700)*
3. *Verify packaged tissues have appropriate labels and recovery records are accurate and complete. (D5.600, D5.700)*
4. *Review time limits for transporting tissue. (D5.800, D5.810)*
5. *Review validation of packaging/transport condition, if utilized. (D5.800)*
6. *Review storage temperature records. (D5.700)*
7. *Review the SOPs to ensure donor reconstruction requirements are included. (D5.900)*
8. *Review selected donor records for documentation of post recovery reconstruction. (D5.900)*

12

Training Program

Suggested Objective Evidence/Guidance:

1. *Review selected training records and documentation for evidence that the program is implemented and active and that employees have received appropriate training. (J2.100)*
2. *Review continuing education documentation. (B2.210)*
3. *Review selected training records for completeness, accuracy, and currency. (J2.400)*
4. *Review job descriptions. Are job descriptions complete and accurate? (B2.320, B2.122)*
5. *Review the Director's job description and CV. How does the tissue bank ensure that the Director is qualified? (B2.110)*
6. *Review the Medical Director's job description. Is the job description complete and accurate? (B2.122)*
7. *Review training materials for obtaining authorization/consent, performing next of kin/historian interviews, conducting physical assessments, and creating donor records. (J2.100, J2.400)*
8. *Interview staff to ascertain their understanding of procedures. (J2.100)*
9. *Interview staff, are they familiar with safety procedures? (J3.200)*
10. *Review CVs of key personnel and technical staff. Are key personnel and technical staff qualified? (B2.310)*
11. *Review how technical staff demonstrate competency. Is this adequate and current? (J2.200)*
12. *Review competency testing. Are files complete and accurate? (J2.200)*

VI. DONOR RECORD SAMPLING PLAN

When donor records are examined, you may wish to use the following Sampling Plan to obtain an adequate number of records to sample:

**DONOR RECORD SAMPLING PLAN
INDEX VALUES
(ASSOCIATED ACCEPTABLE QUALITY LEVELS [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.

VII. TRACER AUDIT FORM

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N//A	Required Document Content (Check yes, no, n/a upon review and verification)
Forms mentioned in this chart review document.					<i>You may wish to randomly select one or two donor records and perform a tracer audit (e.g., review all aspects of tissue banking associated with that donor record). In addition to previous items on this list, include the following:</i>
Construction of Records	C2.000				<ul style="list-style-type: none"> • <i>Are forms accurate and complete?</i>
Donor Risk Assessment Interview Form	D4.220				<ul style="list-style-type: none"> • <i>Does the donor risk assessment questionnaire comply with Standards?</i>
Training Records	J2.100 J2.400				<ul style="list-style-type: none"> • <i>Is training satisfactory and are training records complete?</i>
Maintenance and Qualification Records	J5.100 J5.300				<ul style="list-style-type: none"> • <i>Is equipment used for tissue recovery and storage satisfactory, qualified (when needed), and maintained?</i>
SOP	D4.357 K2.210				<ul style="list-style-type: none"> • <i>Are appropriate serology samples and cultures obtained?</i>

TRACER AUDIT (continued)

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N//A	Required Document Content (Check yes, no, n/a upon review and verification)
Traceability	C1.400				<ul style="list-style-type: none"> • Is the tissue traceable by the unique donor identification number?
Labels	D5.700 G3.100				<ul style="list-style-type: none"> • Is labeling correct?
Cleaning Records	D5.500				<ul style="list-style-type: none"> • Was the recovery site cleaned satisfactorily and is there documentation of that cleaning?
Instrument Records	D6.000 J5.300				<ul style="list-style-type: none"> • Were instruments used during the recovery appropriately sterilized and can the instruments/equipment be linked to the donor?
Recovery Records	D5.400				<ul style="list-style-type: none"> • Were time limits (if any) adhered to?
Recovery Records	D5.900				<ul style="list-style-type: none"> • Was there appropriate reconstruction of the donor?
Reagents and Supplies	D6.000 E1.310				<ul style="list-style-type: none"> • Were reagents and supplies satisfactory (e.g., appropriately stored, not outdated, sterile, used according to manufacturer's instructions, and, if required, used on a first-in, first-out basis)

(Describe your sampling plan. Randomly select items from this list to perform traces. Expect a list of donor numbers here. Example: List which donor chart numbers were audited by listening to the recording and verifying the documentation of authorization/consent.)

TRACER AUDIT (continued)

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

VIII. RECOVERY PARTNER AUDIT

Agency: _____ **Audit Date:** _____
Address: _____ **Lead Auditor:** _____
 _____ **Auditor:** _____
Contact: _____ **Auditor:** _____
Title: _____ _____
Purpose: _____
Scope: _____
Type of Audit: On-Site: _____ Paper: _____

Opening Meeting Attendance:

Persons Interviewed over the course of the audit:

Closing Meeting Attendance:

Have there been any major changes since the last audit (e.g., added a recovery partner, change in key personnel [Medical Director, Director, QA Director, etc.], outsourcing of services, change in services provided, etc.)? Yes _____ No _____

If yes, please explain:

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	---------------------------------------------------	------------------------------------------------------

				1 Registrations, Licensures, and Accreditations	
				1. FDA Registration (1271.25) <ul style="list-style-type: none"> • FDA registration • Dates of most recent FDA inspection • Was a 483 issued? 	
				2. Is the recovery agency accredited by AATB? <ul style="list-style-type: none"> • AATB accreditation • Dates of most recent AATB inspection 	
				3. Obtain any other licensures and accreditations.	
				4. Does the recovery agency maintain satellite facilities? (B1.400) <ul style="list-style-type: none"> • Obtain addresses and contact information for satellites 	
				5. Do the satellite facilities follow the tissue bank's SOPs? (B1.400)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				2 General Information	
				1. Is the purpose of the organization clearly defined? (B1.100)	
				2. Is there a governing body, such as a board of directors, or a designated responsible individual with whom policy making authority resides? (B1.200)	
				3. Is the Director responsible for assuring compliance with all current federal, state, and/or local laws and/or regulations and AATB <i>Standards</i> ? (B2.121)	
				4a. Is there a Medical Director? (B2.210) 4b. If yes, obtain copy of current license (B2.210)	
				5. What are the Medical Director's responsibilities?	
				6. Relative to the manufacturing functions in which the recovery agency is engaged, how is the Medical Director or other medical, technical, or scientific guidance documented? (B1.221, B1.300)	
				7. Do the Director and Medical Director attend AATB continuing education events at least once every three years and obtain at least 15 CMEs/CEUs? (Accreditation policies, Section II.G)	
				8. Are there agreements, contracts, or arrangements with other establishments to perform, or for which the recovery agency performs, manufacturing steps relevant to this audit scope? (1271.150, B1.500, B1.510)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				9. Do these written agreements, contracts, or arrangements indicate the nature of the relationships, divisions of tasks performed, division of issues of liability, responsibilities of each party, and associated protocols and procedures? (B1.510)	
				10. Is compliance with <i>Standards</i> required and documented? (B1.500)	
				11. Who establishes donor acceptance criteria by which suitability for recovery is determined? (B2.221)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	<p style="text-align: center;">AATB and FDA Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP / Policy Reference</p>
---	---	-----	------	-------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------

				<p style="text-align: center;">3</p> <p style="text-align: center;">Quality Program—General</p>	
				<p>1. Is a quality program in place specific to the manufacturing steps for which the recovery agency is registered with FDA? (1271.160, K1.000)</p>	
				<p>2. List the person(s) responsible for managing the quality program.</p>	
				<p>3. Is an individual familiar with, but not having performed the specific work being reviewed, responsible for QA review? (B2.410)</p>	
				<p>4. Do QA personnel have responsibility for assuring compliance with the SOPM and regulatory requirements and can they take action when deviations from the SOPM warrants? (B2.420)</p>	
				<p>5. Does QA review and approve required elements for donor screening and recovery before release? (K1.100)</p>	
				<p>6. Are protocols developed, implemented, and documented for the qualification, verification, and validation of significant components of the quality program? (K1.200)</p>	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				4 Standard Operating Procedures Manual (SOPM)	
				1. Is there a current SOP Manual (SOPM) that includes procedures sufficient to comply with regulatory requirements and AATB <i>Standards</i> ? (1271.47, 1271.160, 1271.180, D5.000, D5.300, J1.100, J1.200, Guidance Document #2)	
				2. Is there an SOP defining the control and maintenance of labels and labeling? (K1.100)	
				3. Do procedures define labeling requirements for transport of recovered tissue? (1271.60,1271.265, D5.800)	
				4. Are there procedures in place that ensure compliance with the information sharing requirements of 1271.160 and AATB standards B1.510 and D4.500?	
				5. Are there procedures in place to ensure compliance with good documentation practices and record retention requirements? (1271.270, C1.300, C1.500, C2.000)	
				6. If procedures are implemented that have been supplied by another organization, are these procedures reviewed for compliance and approved by a responsible individual prior to implementation? (1271.180, B2.123)	
				7. Is the Director or designee responsible for reviewing and approving all technical policies and procedures? (B2.123)	
				8. Does the Medical Director review and approve procedures that are medical in nature? (B2.221)	
				9. Is an annual SOP review conducted by a responsible person and is this review documented? (J1.600)	
				10. Does the Medical Director conduct an annual review of SOPs that are medical in nature and is this review documented? (J1.600)	

S = Satisfactory/Yes, N = Nonconformity/No, N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time. Explain why not addressed.)

S	N	N/A	N/C*	<p style="text-align: center;">AATB and FDA Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP / Policy Reference</p>
---	---	-----	------	-------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------

				11. Does the Medical Director establish policies and procedures for handling adverse outcomes? (B2.222)	
				12. Are modifications to procedures approved by the appropriate persons relevant to content and are the reasons for the modifications documented?	
				13. Is there a method to control the current revision status of documents and are documents referenced in the SOPM available at the tissue bank? (J1.900, J1.500)	
				14. Do procedures appear to be followed as written? (J1.300)	
				15. If deviations from procedures are allowed, are the deviations authorized in writing by the person responsible for quality assurance? (B2.420)	
				16. Are procedures readily available to personnel performing the tasks described in the procedures? (1271.180, J1.700)	
				17. Are archived SOPs maintained in historical sequence for at least 16 years after discontinuation? (J1.900)	
				18. If electronic records are maintained, how does the recovery agency ensure compliance with 21 CFR Part 11 and AATB standard C1.120?	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				5 Donor Records:	
				1. Does the record management system ensure that donor records contain all required information? (C2.200)	
				2. For all donor records generated, is documentation made concurrent with each step? (1271.270, C1.100)	
				3. Are donor records available for inspection? (C1.200)	
				6 Quality Program – Laboratory Qualification and Infectious Disease Testing	
				1a. Does the recovery partner contract for laboratory services? (B1.600) (If yes, complete 1b through 1f.)	
				1b. Does the laboratory have proper certification (e.g., CLIA)? (D4.353)	
				1c. Is appropriate documentation retained for contracted and non-contracted laboratory services? (B1.600)	
				1d. Is all required infectious disease testing performed? (1271.85, D4.354)	
				1e. Are laboratory tests required to be performed according to manufacturer’s instructions with FDA licensed, approved, or cleared donor screening test kits? (1271.80, B1.600, D4.353)	
				1f. If a sample is available, are donor serum, plasma, and/or hematopoietic tissue samples archived for ten years after recovery? (D4.357)	
				2. If the recovery partner does not contract for laboratory services, what lab(s) provides required infectious disease test results to processors for cadaveric blood drawn at recovery?	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time. Explain why not addressed.)

S	N	N/A	N/C*	<p style="text-align: center;">AATB and FDA Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP / Policy Reference</p>
---	---	-----	------	-------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------

				<p>3. What lab(s) may be involved in cases of shared recoveries with the local organ procurement agency?</p>	
				<p>4. Is there a procedure that ensures that blood samples are collected at the time of recovery or within seven days prior to or after donation? (1271.80, D4.351)</p>	
				<p>5. How does the recovery partner ensure that laboratory specimens (blood samples, recovery cultures, etc.) are properly obtained and labeled with a unique donor identifier? (C1.400)</p>	
				<p>6. Is a blood sample from the birth mother collected and tested instead of a specimen from the donor if the donor is one month of age (28 days) or less? (D4.351)</p>	
				<p>7. Is there a procedure for notifying appropriate parties of confirmed positive test results? (D4.356)</p>	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				7 Quality Program – Audits, CAPA, QA, QC	
				1. Is there an audit program managed by quality assurance staff? (1271.160, B2.420, K1.100)	
				2. Does the audit program provide for, at minimum, a documented annual internal audit of all major operational systems? (K5.000)	
				3. Is there a procedure for identifying and investigating nonconformities?	
				4. Is there a corrective action program and corresponding procedure(s) for corrective actions? (1271.160, K4.000)	
				5. Does the corrective action program include tracking the effectiveness of corrective actions? (1271.160)	
				6. How are internal errors and accidents investigated and documented and who investigates and reviews final action regarding errors and accidents? (K4.100)	
				7. How are adverse outcomes and customer complaints investigated and documented? (K4.200)	
				8. Is there a procedure in place for documenting complaints received from processing partners regarding activities the recovery partner performed on behalf of the processing partners? (K4.200)	
				9. Is there a procedure that defines the responsibilities of the recovery partner regarding a processor-initiated adverse event or recall? (K4.310)	
				10. Are computers equipped with appropriate security and back up capabilities? (1271.270, K6.100, K6.300, K6.400)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				11. Is there a quality control program and are key elements defined? (K2.000)	
				12. Are appropriate QC procedures defined to address key elements? (K2.000)	
				8 Materials Management	
				1. Is there a vendor qualification program?	
				2. Are procedures in place to document the receipt of items used at recovery, including the type, quantity, manufacturer, lot number, receipt date, and expiration or date of manufacture? (1271.210, K1.100)	
				3. Does the materials management program include a first in, first out system of supply rotation and a quarantine process for items not yet inspected for release for recovery? (E1.310)	
				4. Are reagents stored according to manufacturers' instructions? (D6.000)	
				5. Are all instruments, solutions, and supplies used for recovery sterile? (D6.000)	
				9 Equipment	
				1. Obtain an equipment inventory relevant to audit scope.	
				2. Is equipment appropriately sized, designed, and located to facilitate use, cleaning, and maintenance? (J5.100)	
				3. Is equipment operated according to the manufacturer's recommendations or the SOP if modifications to these recommendations are made? (J5.200)	

S = Satisfactory/Yes, N = Nonconformity/No, N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time. Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				4. Is there an equipment maintenance and calibration program?	
				5. Are non-disposable surgical instruments and parts of mechanical/electrical equipment that come into contact with tissue during recovery, properly cleaned, disinfected, and sterilized between donor recoveries according to written procedures? (D6.000)	
				6. If recovery instrument sterilization is performed by an outside vendor, are sterilization records readily available for review? (Check vendor qualification program and agreements for sterilization services.)	
				7. If recovery instrument sterilization is performed by an outside vendor, are vendor sterilization procedures available for review?	
				8a. Does the organization recover dura mater, vertebrae, or ocular tissues? (If yes, complete 8b and 8c.)	
				8b. If yes, are instruments used to recover such tissue that are known to have come in contact with tissue from a donor suspected or confirmed to have a prion-associated disease, removed and destroyed? (J5.400)	
				8c. If these instruments were subsequently used to recover tissue from other donors, are these tissues quarantined, withdrawn, and/or recalled? (J5.400)	
				9. Is each storage unit (for tissue) identified and labeled with the general nature of the contents? (J5.500)	

S = Satisfactory/Yes, N = Nonconformity/No, N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time. Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------------------------	--------------------------------------------------------------

				10 Facilities	
				1. Is the tissue bank clean and orderly with adequate plumbing, drainage, lighting, ventilation, and space to prevent mix ups and cross contamination? (1271.190, J4.100, J4.200)	
				2. Does the tissue bank have an on-site recovery suite?	
				3. Are procedures in place and records available regarding documenting routine cleaning and facility inspection to minimize the introduction, transmission, or spread of relevant communicable diseases? (1271.190, J4.000)	
				4. Are procedures in place to perform environmental monitoring appropriate to the manufacturing steps in which the tissue bank is engaged? (J4.300)	
				5. Is a recovery site assessment performed prior to each recovery? (D5.500)	
				6. Is the recovery site cleaned prior to each recovery according to established procedures? (D5.510)	
				7. What percentage of recoveries takes place in: <ul style="list-style-type: none"> • Hospital operating rooms • Hospital morgues • Coroner/ME morgues • Funeral homes, or • On-site recovery suites? 	
				8. Who performs the tissue recoveries e.g.: <ul style="list-style-type: none"> • The recovery organization • Funeral home personnel • Morgue personnel • Medical examiner's office personnel • Surgeons? 	
				9. Do all recoveries take place in a secure, limited access location that meets recovery suitability requirements listed in D5.501?	

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	------------------------------------------------	--------------------------------------------------------------

				10. Are there established procedures to ensure that aseptic or clean technique is utilized through all phases of the recovery process? (D5.500)	
				11. Are recoveries performed according to a prescribed sequenced, zone recovery? (D5.520, AATB Guidance #2)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				11 Recovery Process	
				1. How are donor referrals managed?	
				2. Does the recovery partner obtain an acceptable Document of Gift/Authorization or Informed Consent in writing in accordance with anatomical gift acts, federal, state, and/or local laws and D2.100?	
				3. Do state regulations allow for first person consent / authorization? If yes, is there a defined process for handling first person consent / authorization? (D2.100)	
				4. Is acceptable documentation obtained for the Document of Gift? (D2.310)	
				5. Does the Document of Authorization contain all required signatures, addresses, and phone numbers? (D2.310)	
				6. Does the Document of Authorization contain all of the core elements? (D2.400)	
				7. Is the informed consent/authorization process conducted by the recovery partner or by a contracted agency?	
				8. If conducted by a contracted agency, does the recovery partner control the content of the informed consent/authorization document?	
				9. Regardless of who conducts the informed consent/authorization process, does the recovery partner ensure that all required elements of informed consent/authorization are met? (D2.300)	
				10. Is there evidence that the consenting/authorizing person understood the authorization/consent process, was able to ask questions, and appeared to make an informed decision without coercion? (D2.200)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	<p style="text-align: center;">AATB and FDA Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP / Policy Reference</p>
---	---	-----	------	-------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------

				11. Is there a defined policy, procedure, or program describing tissue donation follow-up that is offered to the Authorizing/Consenting Person (or Party)? (D2.600)	
				12. Is a unique donor identification number assigned to each donor prior to recovery that allows for tracking from the time of referral to the time of final disposition? (1271.290, C1.400, D5.200)	
				13. Does it appear that monetary compensation is not offered to the donor, next of kin, the donor's estate, or third party? (D3.000)	
				14. Is an acceptable donor risk assessment interview performed with an appropriate historian knowledgeable of the donor's relevant medical and social history to screen for the risk of relevant communicable diseases? (Appendix II)	
				15. Is the donor risk assessment interview performed by the recovery partner or by a contracted agency?	
				16. If conducted by a contracted agency, does the recovery partner control the content of the donor risk assessment interview?	
				17. 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? (D4.230/D4.240)	
				18. Is a physical assessment performed prior to recovery to help ensure the donor exhibits no clinical evidence of relevant communicable diseases? (1271.50, D4.210, AATB Guidance #1)	
				19. If tissue is obtained from living donors, are standards followed regarding physical examination and donor risk assessment? (D4.211/D4.220)	
				20. Is tissue not recovered from a donor who may exhibit any disease in AATB standard D4.310?	

S = Satisfactory/Yes, N = Nonconformity/No, N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time. Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				21. If dura mater is recovered, does a qualified pathologist examine the donor's brain per standard D4.310?	
				22. Does the Medical Director evaluate the tissue for eligibility for transplant that exhibits adverse conditions listed in D4.320?	
				23. Does the Medical Director evaluate donors with a history of malignancies? (D4.340)	
				24. Is there an acceptable plasma dilution procedure? (1271.80, D4.352)	
				25. Are age criteria established that meet applicable standards? (D4.400)	
				26. Prior to recovery, do recovery technicians confirm appropriate informed consent / authorization was obtained and confirm that types of tissue to be recovered correspond to the tissues that are authorized / consented? (D5.110)	
				27. Are safety precautions followed as required by <i>Standards</i> ? (J3.100, J3.200, J3.300, J3.400, J3.500, J3.600, J3.700)	
				28. Prior to recovery, is donor verification documented according to established procedures? (D5.120)	
				29. Is adherence to specified tissue recovery time limits documented? (D5.000, D5.400)	
				30. Do recovery records document all required information? (D5.600)	
				31. Are recovered tissues individually and aseptically wrapped and labeled with the unique donor identification number and tissue type? (D5.700)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------------------------	--------------------------------------------------------------

				32. Is there a procedure for respectful reconstruction or care of the donor body following recovery? (D5.900)	
				33. Are tissues maintained at defined environmental temperatures until transport to the processing facility? Are these temperatures documented? (D5.700)	
				34 . Do recovery partner shipping procedures define transport time requirements and shipping protocol, or are these provided by the processor? (D5.800)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

S	N	N/A	N/C*	AATB and FDA Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	----------------------------------------	------------------------------------------------------

				12 Training Program	
				1. Is there a training program that documents competent performance of assigned tasks? (1271.170, J2.000)	
				2. Does the training program for technical and QA staff include all required elements specified in the <i>Standards</i> ? (J2.100, J2.400, J3.000)	
				3. Are current and accurate job descriptions available for technical and QA staff? (B2.122)	
				4. Is there a current signature log documenting names, signatures, initials and dates for technical and QA staff? (K1.100)	
				5. Does the training program include an annual review of all procedures relevant to job descriptions? (J2.400)	
				6. How is competency assessed and documented? (J2.200)	
				7. Does training record documentation include the required elements of J2.400?	
				8. Do the technical staff members participate in appropriate continuing education activities? (J2.300)	
				9. Prior to implementing a new/revised procedure, is training provided to staff? (J1.400)	

S = Satisfactory/Yes,

N = Nonconformity/No,

N/A = Not Applicable,

N/C = Not Covered

*(Function is performed, but not audited at this time.
Explain why not addressed.)

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
2a. Donor Physical Examination Form	D4.200				<ul style="list-style-type: none"> ✓ Verify that one or more facts are correct (or you may choose to verify something else in the chart). _____ ✓ Verify name of examiner: _____ ✓ Verify completion of the form
2b. Donor Risk Assessment Interview	D4.220				<p>Are the following items present?</p> <ul style="list-style-type: none"> • Donor Name • Relationship of donor to Authorizing/Consenting Person • Name of the interviewee • Name of the interviewer <ul style="list-style-type: none"> ✓ Verify completion of all applicable questions.
2c. Preliminary Donor Medical History	D4.230				<ul style="list-style-type: none"> ✓ Verify that a preliminary review of the donor history was conducted. (May be in the form of a donor work-up sheet or a donor referral.)
2d. Medical Records	D4.230				<ul style="list-style-type: none"> ✓ Verify that relevant medical records or a summary of relevant medical records is available for Medical Director review.
2e. Donor Autopsy Report	D4.240				<ul style="list-style-type: none"> ✓ When applicable, verify autopsy report is a record in the donor chart or is being pursued.
2f. Plasma Dilution	D4.352				<ul style="list-style-type: none"> ✓ When applicable, verify completion of the plasma dilution worksheet.

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
2g. Blood Testing	D4.354				<ul style="list-style-type: none"> ✓ Verify testing results. <ul style="list-style-type: none"> • anti-HIV-1 • anti-HIV-2 • Nucleic acid test (NAT) for HIV-1 • Hepatitis B (HBsAg) • Total antibody to hepatitis B core antigen (anti-HBc- total meaning IgG and IgM) • Hepatitis C (anti-HCV) • Nucleic acid test (NAT) for HCV • anti-HTLV-I (if applicable) • anti-HTLV-II (if applicable) • Syphilis • Other
2h. Age Criteria	D4.400				Are age requirements met?
3a. Donor Recovery	C1.100 D5.000				Is donor recovery documentation present and complete?
3b. Donor Identity	D5.120				<ul style="list-style-type: none"> ✓ Verify donor identity ✓ Source of donor verification
3c. Recovery Records	D5.600				<ul style="list-style-type: none"> ✓ For tissue other than autologous tissue, verify recovery records contain: <ul style="list-style-type: none"> • Name and address of recovery agency • Date, time, and staff involved in the recovery • Location of the tissue donation within the recovery site facility, if relevant • Donor name, age, and gender • Type, lot number, manufacturer, and expiration date of supplies and reagents used to recover, rinse, and transport tissue • Specific tissues recovered

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
3d. Tissue Recovery Cultures	D5.521				If recovery cultures are obtained, is the technique used to obtain the cultures of recovered tissue appropriate for the tissue type and performed according to written instructions?
3e. Post-Recovery	D5.600 D5.900				<ul style="list-style-type: none"> ✓ Verify post-recovery records <ul style="list-style-type: none"> • Documentation of deceased donor reconstruction • Final disposition
3f. Sharing of Records	D4.500				<ul style="list-style-type: none"> ✓ Verify that information has been shared as required. <p>Is the information system:</p> <ul style="list-style-type: none"> • Timely • Clear • Documented
3a. Certified Death Certificate (if applicable)	D4.230				<ul style="list-style-type: none"> ✓ 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?
3b. Cause of Death	D4.230				<ul style="list-style-type: none"> ✓ 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