

American Association of Tissue Banks

Self-assessment Tool/Audit Report (STAR)

For

Non-Transplant Anatomical Donation Organizations (NADO)



September 2011

Organization:	Audit Date:
Address:	Lead Auditor:
	Auditor:
Contact:	Auditor:
Title:	Purpose of Audit:
	Scope of Audit:
	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 partner, change in key personnel [Physician Advisor, Director, QA Director, etc.], outsourcing of services, change in services provided, etc.)? Yes _____ No _____

If yes, please explain:

AUDIT CONFIRMATION

Check Type of Audit

	Internal Audit of NADO	Audit Date(s):
	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 for previous year's audit.**
- 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 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

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

				1 REGISTRATIONS, LICENSURES, AND ACCREDITATIONS	
				1. Is the Non-Transplant Anatomical Donation Organization (NADO) accredited by AATB? <ul style="list-style-type: none"> • Dates of most recent AATB inspection • Date last accredited 	
				2. Obtain any other licensures and accreditations and list below.	
				3. Does the NADO maintain satellite facilities? (NT-B1.400) <ul style="list-style-type: none"> • Obtain address and contact information for satellite(s) 	
				4. Do the satellite facilities follow the tissue bank's SOPs? (NT-B1.400)	
				2 GENERAL INFORMATION	
				1. Is the purpose of the organization clearly defined? (NT-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? (NT-B1.200)	
				3a. Is the Director responsible for establishing policies regarding ethical practices and behavior consistent with direction from the governing body? (NT-B2.121)	
				3b. Is the Director responsible for all operations, including compliance with the <i>Standards</i> and applicable laws and regulations?	
				4. Does the Director attend AATB continuing education events at least once every three years and obtain at least 15 CMEs/CEUs? (Accreditation policies, Section II.G)	
				5a. What is the name of the Physician Advisor? (NT-B2.210)	

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 Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP / Policy Reference</p>
---	---	-----	------	---	---

				5b. Obtain a copy of current license. (NT-B2.220)	
				6. Does the Physician Advisor, upon request, provide advice or information regarding medical issues? (NT-B2.210)	
				7. Does the Physician Advisor provide consultation for establishing procedures for performing donor acceptability assessment and for designing a donor screening and testing plan? (NT-B2.230)	
				8. Relative to the manufacturing functions in which the NADO is engaged, how is guidance documented that is received from the Physician Advisor or other medical, technical, or scientific guidance? (NT-B1.300)	
				9. Do technical staff members appear to be qualified? (NT-B2.310)	
				10. Are there agreements, contracts, or arrangements with other organizations to perform, or for which the NADO performs, manufacturing steps relevant to this audit scope? (NT-B1.500, NT-B1.510)	

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

				11a. Do these written agreements, contracts, or arrangements indicate: <ul style="list-style-type: none"> • The nature of the relationships • Division of tasks performed • Division of issues of liability • Specific responsibilities of each party, and • A summary of the protocols and procedures relating to the services provided? (NT-B1.510) 	
				11b. Is compliance with <i>Standards</i> required and documented? (NT-B1.500)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--------------------------------	---

				3 QUALITY PROGRAM—GENERAL	
				1. Is a quality program in place that addresses the required elements of the <i>Standards</i> including the AATB Accreditation Policies? (NT-L1.100, Accreditation Policies)	
				2. List the person(s) responsible for managing the quality program.	
				3. Is an individual familiar with, but not having performed the specific work being reviewed, responsible for QA review? (NT-B2.410)	
				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? (NT-B2.420)	
				5. Does QA review and approve required elements for donor screening and preparation records before release? (NT-L1.100)	
				6. Are protocols developed, implemented, and documented for the qualification, verification, or validation of significant components of the quality program? (NT-L1.200)	
				7. Following repairs and system upgrades, is equipment re-qualified according to the SOPM? (NT-K5.310)	
				8. If NAM to be shipped requires specific environmental conditions (other than ambient temperature) is the capability of the transport package to maintain the required environmental conditions validated/demonstrated? (NT-H4.200)	
				9. Is the length of time that the transport package can maintain specified environmental conditions determined and documented? (NT-H4.200)	
				10. Are computers equipped with appropriate security and back up capabilities? (NT-L4.100, NT-L4.300, NT-L4.400)	

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 Requirements	
				Questions	Notes, Objective Evidence, SOP / Policy Reference

				4	
				QUALITY PROGRAM – AUDITS, CAPA, QC	
				AUDITS	
				1. Is there an audit program managed by quality assurance staff? (NT-B2.127, NT-L1.000, NT-L1.100)	
				2. Does the audit program provide for, at minimum, a documented annual internal audit of all applicable major operational systems? (NT-L3.000)	
				3. If laboratory testing is performed for the NADO, does the NADO ensure through paper or on-site audit that the laboratory performing infectious disease testing follows manufacturer's instructions and is appropriately certified? (NT-B1.600)	
				CAPA	
				1. Is there a procedure for identifying and investigating nonconformities?	
				2. Is there a corrective action program and corresponding procedure(s) for corrective actions? (NT-L2.000)	
				3. Are internal errors and accidents investigated and documented and who investigates and reviews final action regarding errors and accidents? (NT-L2.100)	
				4. Are complaints investigated and documented? (NT-L2.200)	
				5. Are unexplained discrepancies or deviations from specifications fully investigated and documented? (NT-F3.000)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--	--

				QC	
				1. Are labels are approved by QA staff prior to release for use and is there documentation of date of receipt, date of inspection, and names of staff involved in label receipt and inspection? (NT-H2.320)	
				2. If NAM is prepared by another organization, does the NADO assure that the preparation and QC records of that organization are retained as required? (NT-C4.000)	
				3. Are quality control measures performed and found acceptable prior to NAM release? (NT-F1.200)	
				4. Does quality assurance verify completion of, and Director's or designee's signature, on the donor acceptability assurance and quality control review prior to release of NAM to inventory? (NT-F1.300)	

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 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;">5</p> <p style="text-align: center;">QUALITY PROGRAM – LABORATORY QUALIFICATION AND INFECTIOUS DISEASE TESTING</p>	
				1a. Does the NADO contract for or perform laboratory testing services? (NT-B1.600) (If yes, complete 1b through 1d.)	
				1b. Does the laboratory have proper certification (e.g., CLIA)? (NT-B1.600)	
				1c. Are laboratory tests required to be performed according to manufacturer’s instructions? (NT-B1.600)	
				1d. Is appropriate documentation retained for contracted and non-contracted laboratory services? (NT-B1.600)	
				2. Is NAM from donors with positive laboratory test results not released for use unless specifically requested and labeled accordingly? (NT-D5.230)	
				3. If the donor screening and testing plan does not include laboratory testing of donor blood samples, is specific NAM labeling used to alert educators/researchers that testing has not been performed so they can agree to accept the risks or not? (The donor screening and testing plan does not need to include laboratory testing of blood samples if NAM remains in the same institution) (NT-D5.230)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--------------------------------	---

				6 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> ? (NT-D5.000, NT-E1.000, NT-K1.100, NT-K1.200)	
				2. Are there SOPs for all activities performed (e.g., informed consent/authorization, NAM acquisition, NAM preparation and handling, laboratory procedures for tests performed in-house, labeling, traceability, quality assurance and quality control, equipment maintenance, personnel training, etc.)? (NT-K1.200)	
				3. Are there procedures in place that ensure compliance with the information sharing requirements of NT-B1.510 and NT-L1.100?	
				4. Are there procedures in place to ensure compliance with good documentation practices and record retention requirements? (NT- C1.300, NT-C1.400, NT-C1.500, NT-C2.000)	
				5. Do procedures for NAM acquisition comply with <i>Standards</i> ? (NT-D6.000)	
				6. Are there SOPs for collecting and initially reviewing readily available medical information? (NT-D5.220)	
				7. Is there a procedure(s) for notifying appropriate parties of confirmed positive test results (if laboratory testing is performed) that contains the elements required by <i>Standards</i> ? (NT-D5.231)	
				8. Are there procedures to preserve the dignity of the donor including protecting the confidentiality of identifiable information and the appropriate use of video, camera, and other imaging equipment? (NT-D6.310)	
				9. Are there procedures for preventing the release of images and identifiable information? (NT-D6.310)	
				10. Are there procedures for identifying the presence of radioactive implants, evaluating them, and following the planned course of action when such implants are present to prevent unsafe exposure to radioactive materials? (NT-D5.241)	

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 Requirements	
				Questions	Notes, Objective Evidence, SOP / Policy Reference

				11. Are there SOPs to document, handle, and disseminate personal property of the deceased donor? (NT-D6.310)	
				12. If multiple donors are prepared simultaneously, are there written SOPs to prevent contamination and cross-contamination by NAM during preparation? (NT-E1.200)	
				13. Are there procedures in place to detect temperature excursions outside of acceptable limits and what to do with NAM if subjected to unacceptable storage conditions? (NT-E4.200)	
				14. Are there procedures for the emergency transfer of NAM to designated alternative storage facilities and for alternative storage and monitoring methods in the event of mechanical failure and what actions to take when tolerance limits have been exceeded? (NT-E4.400)	
				15. Do emergency transfer procedures include specification of temperatures and time limits (tolerance limits) related to the emergency transfer? (NT-E4.400)	
				16. Do procedures regarding NAM distribution review define the responsibilities of each donor record reviewer? (NT-F1.000)	
				17. Are there procedures for confirming the final disposition of each NAM distributed to an Educator/Researcher to ensure compliance with written requests and contracts? (NT-J1.110)	
				18. Is there a procedure(s) for evaluating and approving requests for NAM that include the criteria in NT-G1.200?	
				19. Is there a procedure(s) to ensure that correct labels, labeling, and packaging materials are used? (NT-H2.100)	
				20. Is there a procedure(s) for re-labeling that specifies the conditions under which re-labeling may occur and the staff authorized to perform re-labeling activities? (NT-H2.200)	
				21. Are there appropriate labeling control procedures? (NT-H2.300)	
				22. Is there a procedure(s)/policy for authorizing or prohibiting the return of NAM? (NT-H8.000)	
				23. Does the final disposition procedure(s) have policies consistent with informed consent/authorization and applicable laws and regulations, including determining which NAM may be disposed of as medical or biological waste? (NT-J1.100)	
				24. If automated data processing is used for decision-making are there adequate procedures to prevent inaccurate input or output of data and programming errors? (NT-L4.200)	

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 Requirements	
				Questions	Notes, Objective Evidence, SOP / Policy Reference

				25. 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? (NT-B2.126)	
				26. Is the Director responsible for reviewing and approving all technical and medical policies and procedures? (NT-B2.123)	
				27. Is an annual SOP review conducted by the Director or designee and is this review documented? (NT-K1.600)	
				28. Does the Director conduct an annual review of SOPs for donor acceptability and adverse events and is this review documented? (NT-K1.600)	
				29. Are modifications to procedures approved by the Director or designee relevant to content and are the reasons for the modifications documented? (NT-K1.400)	
				30. Is there a method to control the current revision status of documents and are documents and publications referenced in the SOPM available at the NADO? (NT-K1.400, NT-K1.500, NT-K1.900)	
				31. Do procedures appear to be followed as written? (NT-K1.300)	
				32. If deviations from procedures are allowed, are the deviations authorized in writing by the Director or designee? (NT-K1.400)	
				33. Are procedures readily available to personnel performing the tasks described in the procedures? (NT-K1.700)	
				34. Are archived SOPs maintained in historical sequence for at least 10 years after discontinuation? (NT-K1.900)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--------------------------------	---

				7 RECORDS	
				DONOR RECORDS	
				1. Does the record management system ensure that donor records contain all required information and that the records are complete, indelible, legible, and accurate? (NT-C2.100)	
				2. For all donor records generated, is documentation made concurrent with each step and does this documentation indicate the dates and identities of the staff involved in each significant step of the operation from NAM acquisition through final distribution? (NT-C1.100, NT-C1.400)	
				3. Are donor records and NAM traceable? (NT-C1.400)	
				4. Are the results of donor acceptability assessment maintained by the NADO? (NT-C1.110)	
				5. Is access to donor identity and associated records restricted to NADO staff with a need for access, applicable NADOs involved in multi-facility activities, and educators/researchers of NAM with a need for access? (NT-C1.200)	
				6. Are donor records available for inspection? (NT-C1.200)	
				7. Is the Document of Gift/Authorization/Informed Consent maintained in the donor's record at the organization responsible for acquisition? (NT-D2.100, NT-D3.100)	
				8. Is The Document of Gift/Authorization/informed Consent maintained in the donor's record at the NADO that is responsible for donor acceptability assessment? (NT-D3.100)	
				9. Is the authorization expressed in a Document of Gift/Authorization? (NT-D2.100)	
				10. Does the Document of Authorization contain the items and signatures listed in NT-D2.320?	
				11. Does the Informed Consent Record comply with applicable laws and regulations? (NT-D3.300)	
				12. Does the Informed Consent Record include the requirements listed in the <i>Standards</i> ? (NT-D3.300)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--------------------------------	---

				13. Once NAM is released, does the donor record contain a release statement and signature of the Director or designee who is responsible for donor acceptability determination, and if different, the individual(s) responsible for reviewing all technical and quality control specifications? (NT-F1.000)	
				14. If NAM is distributed under exceptional release, is documentation of the exceptional release, based on the proposed use of NAM, maintained in the donor record? (NT-F2.200)	
				15. Are records of exceptional release maintained together or summarized in a log? (NT-F2.200)	
				16. If a donor or the NAM is deemed unacceptable for any reason, are the findings documented in the donor record? (NT-F3.100, NT-F3.200)	
				GENERAL RECORDS	
				1. Are records in English, or if in another language, translated to English and accompanied by a statement of authenticity by the translator? (NT-C2.100)	
				2. Is there a mechanism to establish chain of custody for NAM acquisition through final disposition? (NT-C1.400)	
				3. Do acquisition records document all required information? (NT-D6.500)	
				4. Are records created to document NAM preparation and do these records contain the elements required by <i>Standards</i> ? (NT-E2.000)	
				5. Do quarantine records indicate the reason for quarantine and the date of entry and release to distribution inventory? (NT-E3.300)	
				6. Are requests for NAM intended for education and/or research submitted and documented? (NT-G1.000)	
				7. Are requests for NAM documented including: how the NAM will be used and the name, address, and affiliation of the educator/researcher? (NT-G1.000)	
				8. Do requests for NAM include all of the information required in NT-G1.100?	
				9. Are requests for NAM evaluated according to the SOP? (NT-G1.200)	
				10. Do distribution records contain all required information as specified in NT-H7.100?	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--	--

				11. Does documentation of final disposition include all elements required in NT-J1.110?	
				12. Is information pertaining to the return of NAM recorded in the final disposition record and does the information include the requirements in NT-H8.000? (NT-H8.000)	
				13. If electronic records are maintained, is there a system in place to ensure the integrity of electronic records and that information is retrievable and able to be printed as a hard copy on demand? (NT-C1.120)	
				14. Are applicable records retained at least 10 years beyond the intended date of final disposition or longer if required by applicable laws and regulations? (NT-C1.300)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--	--

S	N	N/A	N/C*	8 MATERIALS MANAGEMENT	
				1. Is there a vendor qualification program?	
				2. Are instruments, supplies, and reagents used according to manufacturer's instructions? (NT-E1.400)	
				3. Are instruments used to prepare NAM clean and disinfected? (NT-E1.410)	
				4. Are non-disposable supplies cleaned, disinfected, or sterilized between use for donors to prevent contamination and cross-contamination? (NT-E1.420)	
				5. Are reagents stored according to manufacturers' instructions? (NT-E1.430)	

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 Requirements Questions	Notes, Objective Evidence, SOP / Policy Reference
---	---	-----	------	--------------------------------	---

				9 EQUIPMENT	
				1a. Obtain an equipment inventory relevant to audit scope.	
				1b. Is equipment appropriately sized, designed, and located to facilitate use, cleaning, and maintenance? (NT-K5.100)	
				2. Are non-disposable instruments and mechanical/electrical equipment used in preparation cleaned and disinfected between use for different donors according to written procedures to prevent contamination and cross-contamination? (NT-E1.410)	
				3. Is equipment operated according to the manufacturer's recommendations or the SOP if modifications to these recommendations are made? (NT-K5.200)	
				4. Is equipment, laboratory instruments, apparatuses, gauges, and recording devices qualified, maintained, inspected, monitored, cleaned, sterilized, disinfected, decontaminated, and repaired at appropriate intervals in accordance with the SOPM and schedules? (NT-K5.300)	
				5a. Who sterilizes instruments?	
				5b. If instrument sterilization is performed by an outside vendor, are sterilization records readily available for review? (Check vendor qualification program and agreements for sterilization services.)	
				6. Is equipment cleaned, sterilized, or decontaminated at appropriate intervals in accordance with the SOPM to prevent malfunction, contamination, cross-contamination, or accidental exposure to blood-borne pathogens? (NT-K5.400)	
				7a. Does the organization recover dura mater, vertebrae, or ocular tissues? (If yes, complete 8b and 8c.)	
				7b. 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? (NT-K5.400)	
				7c. If these instruments were subsequently used to recover NAM from other donors, are these NAM removed and destroyed? (NT-K5.400)	
				8. Is each storage unit (for tissue) identified and labeled with the general nature of the contents? (NT-K5.500)	

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

				<p>9. Are mechanical storage units used for storing NAM, reagents, media, refrigerants, or other laboratory solutions not used for storing food and/or liquids for human consumption and marked accordingly? (NT-E4.300)</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*	<p style="text-align: center;">AATB 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;">10</p> <p style="text-align: center;">FACILITIES</p>	
				<p>1. Is the physical plant clean and orderly with adequate plumbing, drainage, lighting, ventilation, and space to prevent mix ups and cross contamination? (NT-K4.100, K4.200)</p>	
				<p>2. Does the preparation site have adequate designated space (e.g., lockable doors, adequate construction, equipment, and furniture, working sinks and adequate drainage, etc.)? (NT-E1.100)</p>	
				<p>3. Are procedures in place and records available regarding documenting routine scheduled cleaning and facility inspection to minimize the introduction, transmission, or spread of relevant communicable diseases? (NT-K4.210)</p>	
				<p>4. Are work surfaces decontaminated that were used in preparing neurological material, including dura mater, vertebrae, or ocular tissues, that are known or suspected to have prion-associated disease? (NT-K4.220)</p>	
				<p>5. Does the NADO maintain adequate physical security to safeguard NAM inventory and records and to prevent entry of unauthorized individuals? (NT-K4.300)</p>	
				<p>6. Do only those personnel (including inspectors) who are authorized enter areas of the building or facility designated as limited-access areas? (NT-K4.300)</p>	

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

11 NAM ACQUISITION					
				1. Are all donor referrals documented? (NT-D1.000)	
				2. Does referral for donation for transplant take precedence over referral for NTAD, if possible? (NT-D1.000)	
				3. Are incentives not offered to referral sources that result in encouraging families to choose donation for research and/or education over donation for transplantation and/or therapy? (NT-D1.000)	
AUTHORIZATION					
				1. Is an acceptable Authorization to acquire NAM obtained in writing in accordance with anatomical gift acts and other applicable laws and regulations and NT-D2.100?	
				2. Is there evidence that the Authorizing Person understood the authorization process, was able to ask questions, and appeared to make an informed decision without coercion? (NT-D2.200)	
				3. When the donor has executed a Document of Gift is it acted upon only if it meets applicable laws and regulations? (NT-D2.310)	
				4. What methods are used to obtain Authorization? <ul style="list-style-type: none"> • In person • By telephone • Facsimile • Electronic transmission 	
				5. Does the Authorization process comply with requirements in NT-D2.330?	
				6. Does the Document of Authorization contain all of the core elements? (NT-D2.400)	
				7. Is required information provided to the Authorizing Person (NT-D2.400)?	
				8a. Is the Authorization process conducted by the NADO or by a contracted agency?	
				8b. If conducted by a contracted agency, does the NADO control the content of the Document of Authorization? (NT-D2.400)	
				9. Regardless of who conducts the authorization process, does the NADO ensure that all required elements of informed consent/authorization are met? (NT-D2.300)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

NOTIFICATION OF GIFT					
				1a. When the gift is authorized by a donor's own Document of Gift (i.e. first person consent) and where law mandates notification, is this notification made according to state law? (NT-D2.500)	
				1b. In all other cases, prior to transport of the body or acquisition, does the donation coordinator attempt to notify the person who would have been an Authorizing Person (had no gift been made during the life of the donor) or the person who is authorized to make arrangements for final disposition? (NT-D2.500)	
				1c. Does the information provided in the notification contain at least the core elements of authorization? (NT-D2.500)	
				1d. Does the donor coordinator ask whether the notified person is aware of any revocation or refusal made by the donor? (NT-D2.500)	
				1e. Does the donor coordinator not give an opportunity for the recipient of the Notification a chance to revoke or refuse the donation? (NT-D2.500)	
				1f. If Notification is not possible, is the attempt to notify documented? (NT-D2.500)	
				2. Is service to donor families or referral to community services or a support system offered to the Authorizing Person and is this documented? (NT-D2.600)	
INFORMED CONSENT FOR LIVING DONORS					
				1a. Is informed consent obtained from a living donor obtained in accordance with applicable laws or regulations? (NT-D3.100)	
				1b. Is there evidence that the Living Donor understood the authorization process, was able to ask questions, and appeared to make an informed decision without coercion? (NT-D3.200)	
				1c. What methods are used to obtain Informed Consent? <ul style="list-style-type: none"> • In person • By telephone • Facsimile • Electronic transmission 	
				1d. Does the consent process comply with requirements in NT-D3.310?	
				1e. Does the Informed Consent contain all of the core elements? (NT-D3.400)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

DONOR ACCEPTABILITY CRITERIA					
				1. Is a unique donor identification number assigned to each donor prior to acquisition that allows for tracking from the time of acquisition to final disposition? (NT-C1.400, NT-D5.300)	
				2. Does it appear that monetary compensation is not offered to the donor, next of kin, the donor's estate, or third party? (NT-D4.000)	
				3. Are there policies defining inclusion and exclusion criteria for donor acceptability? (NT-D5.100)	
				4. Does the Director, in consultation with the Physician Advisor, establish procedures for performing donor acceptability assessment that include a donor screening and testing plan designed to reduce the risks of transmission of certain infectious diseases? (NT-D5.100, NT-D5.200)	
				5a. Is the donor risk assessment interview performed by the NADO or by a contracted agency?	
				5b. If the donor risk assessment interview is conducted by a contracted agency, does the NADO control the content of the donor risk assessment interview?	
				6. 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? (NT-D5.210)	
				7. Are results from interviews (with donor, donor family, close contacts, healthcare providers, etc.) reviewed by trained personnel for proper interpretation of medical relevance of information obtained? (NT-D5.210)	
				8. Does the Director or designee review and evaluate the medical information or a summary generated by a trained individual? (NT-D5.220)	
				9. 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? (NT-D5.220)	
				10. Is a physical assessment performed prior to acquisition to help ensure the donor exhibits no evidence of high-risk behavior or signs of hepatitis and HIV infection, other viral or bacterial infections, or trauma? (NT-D5.240)	
				11. If established criteria are not met, is the donation deferred? (NT-D5.240, Reference Document V)	

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 Requirements</p> <p style="text-align: center;">Questions</p>	<p style="text-align: center;">Notes, Objective Evidence, SOP/ Policy Reference</p>
---	---	-----	------	---	--

ACQUISITION OF NAM					
				1. Prior to acquisition, do technicians confirm appropriate informed consent / authorization was obtained and documented? (NT-D5.110)	
				2. Prior to NAM acquisition, is donor verification documented according to established procedures? (NT-D6.120)	
				3. Is adherence to specified acquisition time limits documented? (NT-D6.000)	
				4. Is the donor always treated with dignity and respect? (NT-D6.200)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

				12 NAM PREPARATION AND STORAGE	
				1. Does the NAM identifier serve to relate NAM to the donor from whom it was acquired and the associated records at all stages of preparation? (NT-E1.000)	
				2. Is NAM prepared in an aseptic or clean fashion, in an appropriate location, using standard surgical preparation, instrumentation, and technique? (NT-E1.100)	
				3. Prior to preparation is the site evaluated to be suitable using pre-established criteria? (NT-E1.100)	
				4. Is NAM prepared from a single donor and is it the exclusive activity taking place at one time in an isolated space at the preparation site? (NT-E1.200)	
				5. Are there specified time limits for preparation? (NT-E1.300)	
				6. If preparation is delayed, is NAM stored as specified in the SOPM? (NT-E1.300)	
				7. Is there a way to identify and trace NAM during preparation, quarantine, and storage? (NT-E2.000)	
				8. Are NAM quarantine areas physically separated and clearly labeled to distinguish quarantine NAM from NAM acceptable for use? (NT-E3.100)	
				9. Is NAM quarantined at all phases of the operation when its release could affect the quality, safety, packaging, or utility of the NAM? (NT-E3.200)	
				10. Is NAM quarantined until it is determined to be acceptable for use based on criteria in standard E3.200? (NT-E3.200)	
				11. Are defined environmental conditions maintained during storage? (NT-E4.100)	
				12. Are specific environmental conditions for storing NAM in accordance with the SOPM, these <i>Standards</i> , and applicable laws and regulations? (NT-E4.100)	
				13. Are NAM stored at appropriate temperatures to prevent degradation that would have an impact on the acceptability for intended use? (NT-E4.200)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--	---

				13 NAM RELEASE	
				1. Prior to releasing NAM to inventory for use and/or distribution, does the Director or designee determine donor acceptability and does responsible staff members verify that the appropriate donor acceptability assessment has been completed and signed? (NT-F1.000, NT-F1.300)	
				2. Does the Director or designee evaluate all donor information specified in the <i>Standards</i> ? (NT-F1.100)	
				3a. Is exceptional release of NAM permitted? If yes, complete 3b and 3c.	
				3b. If exceptional release is permitted, is there adequate documentation of the required elements in NT-F2.100?	
				3c. Is relevant information that was not available for the NAM distributed under exceptional release provided to the requestor as soon as it's available?	
				4. Is NAM failing any portion of the review process maintained in quarantine pending resolution of final disposition? (NT-F3.000)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

				14 NAM LABELING, PACKAGING, TRANSPORT	
				LABELING	
				1. Are nomenclature and units of measurement used to describe NAM specified in the SOPM and applied consistently? (NT-H1.100)	
				2. Are labels designed to facilitate the use of uniform labeling techniques? (NT-H1.110)	
				3. If pre-printed or computer-generated labels are used, is a list maintained of these labels with an example of each label used and dates of use? (NT-H1.200)	
				4. Do labels adhere firmly to the container under all anticipated storage conditions? (NT-H1.300)	
				5. Are labels clear, legible, and indelible and not removed unless to correct labeling errors? (NT-H1.300)	
				6. Do labeling materials comply with applicable laws and regulations? (NT-H2.100)	
				7. Are reasons for, and events surrounding, re-labeling activities documented? (NT-H2.200)	
				8. Do you verify and document label accuracy and that labeling checks were performed?	
				9. Is the labeling area inspected prior to the start of labeling activities? (NT-H2.300)	
				10. Is access to the labeling area restricted to authorized personnel? (NT-H2.310)	
				11. Prior to labeling, is the package inspected for evidence of defects that could compromise the integrity of the contents or safety of the person handling the package and is there documentation of this inspection? (NT-H2.330)	
				12. Does the package label contain all information required by NT-H3.100?	
				13. Does the package insert contain all information required by NT-H3.200?	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

				14. Does the container label indicate “Non-Clinical Use Only?” (NT-H3.300)	
				15. Does the container label include all information required by NT-H3.300?	
				PACKAGING	
				1. Is NAM packaged in a manner that permits maintenance of required environmental conditions for the duration of transport or as specified by the educator/researcher? (NT-D6.400)	
				2. Is NAM packaging, the transport receptacle, labeling material, and transport methodology compliant with applicable laws and regulations and transporter guidelines? (NT-D6.400)	
				3. Do NAM packages and containers ensure NAM integrity, withstand storage conditions, and maintain quality for the labeled shelf life? (NT-H4.000, NT-H5.000)	
				4. Do NAM packaging and containers comply with applicable laws and regulations and transporter guidelines? (NT-H4.000, NT-H5.000)	
				5. Are packaging and containers designed to not produce toxic residues during storage and to ensure NAM integrity, prevent leakage, and prevent contamination of contents? (NT-H4.100, NT-H5.100)	
				6. Is the expiration date of the transport package indicated on the outside of the transport package (if applicable)? (NT-H4.200)	
				7. Do NAM containers not interfere with effective use of appropriate agents applied to disinfect NAM? (NT-H5.100)	
				8. Are unused containers handled and stored to maintain integrity? (NT-H5.200)	
				9. Is each container visually inspected prior to use and immediately after filling? (NT-H5.30)	
				10. Are damaged containers or containers not meeting specifications not used? (NT-H5.400)	
				11. Are all NAM shipments subjected to a final inspection? (NT-H5.400)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--	---

TRANSPORT					
				1. If NAM is shipped prior to donor acceptability determination, is NAM shipped under quarantine and accompanied by records assuring identification of the donor and indicating that donor acceptability assessment for the NAM has not been performed? (NT-D5.400)	
				2. Does the NAM transport receptacle and transport methodology comply with applicable laws and regulations and transporter guidelines? (NT-H6.100)	
				3. Is the mode of transport determined by the need for any special shipping and handling requirements and/or any shipping refrigerants and the urgency of the request? (NT-H6.100)	
				4. Is NAM moved between physical inventory locations documented and is the date of transfer, staff involved, and verification of receipt if transported by common carrier documented? (NT-H6.110)	
				5. When a NADO transports NAM after release, do all accompanying original labeling or other enclosures accompany the NAM? (NT-H6.120)	

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*	<p style="text-align: center;">AATB 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;">15</p> <p style="text-align: center;">NAM DISTRIBUTION, AND FINAL</p> <p style="text-align: center;">DISPOSITION</p>	
				DISTRIBUTION	
				1. Do distribution records permit NAM to be traced from the donor to the educator/researcher and back? (NT-H7.100)	
				2. If NAM may be returned, is information provided to the organization returning the NAM regarding return procedures, acceptable packaging, and appropriate common carriers? (NT-H8.100)	
				FINAL DISPOSITION	
				1. Is the final disposition of NAM in accordance with applicable laws and regulations? (NT-J1.000)	
				2. Does the final disposition policy comply with standard NT-J1.100?	
				3. Are remains being prepared for final disposition placed in a suitable container and appropriately labeled in accordance with applicable laws and regulations (NT-J1.120)	

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 Requirements Questions	Notes, Objective Evidence, SOP/ Policy Reference
---	---	-----	------	--------------------------------	--

				16 TRAINING AND SAFETY PROGRAM	
				1. Is there a training program that documents competent performance of assigned tasks? (NT-K2.000)	
				2. Does the training program for technical and QA staff include all required elements specified in the <i>Standards</i> ? (NT-K2.100)	
				3. Are current and accurate job descriptions available for technical and QA staff? (B2.122, B2.320)	
				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? (NT-K2.200)	
				7. Does training record documentation include the required elements of NT-K2.400?	
				8. Do technical staff members participate in appropriate continuing education activities? (NT-K2.300)	
				9. Prior to implementing a new/revised procedure, is training provided to staff? (NT-K1.400)	
				10. Does the donor screening and testing plan include precautions for protection of staff and educators/researchers? (NT-D4.100)	
				11. Are safety precautions followed as required by <i>Standards</i> ? (NT-K3.100, NT-K3.200, NT-K3.300, NT-K3.400, NT-K3.500, NT-K3.600, NT-K3.700)	

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.)

DONOR CHART REVIEW

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)	NT-C1.100 NT-D2.320 NT-D2.330 NT-D2.400 NT-D3.100 NT.D3.300 NT-D3.310 NT-D3.400				Are required signatures present? <ul style="list-style-type: none"> • Authorizing/Consenting Person, if applicable • Person obtaining Document of Gift/Authorization/Informed Consent, as applicable • Witness (if applicable)
1b.					Is authorization present from the Authorizing/Consenting Person to acquire tissue and make it available for transplantation?
1c.					<ul style="list-style-type: none"> ✓ Verify that a few selected facts on the Document of Gift/Authorization or Informed Consent and/or other donor records are accurate. <ul style="list-style-type: none"> • Selected authorization/consent fact(s) verified (list) • Other fact(s) verified (list)
1d.					<ul style="list-style-type: none"> ✓ If authorization/consent is obtained via telephone, verify that authorization/consent is: <ul style="list-style-type: none"> • Witnessed (if applicable) • Recorded
1e.					<ul style="list-style-type: none"> ✓ 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 Assessment Form	NT-D5.240				<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 Inquiry Interview	NT-D5.210				<p>Are the following items present?</p> <ul style="list-style-type: none"> • Donor Name • Name of the person providing information including his/her relationship to the donor • Name of the person conducting the inquiry <p>✓ Verify completion of all applicable questions.</p>
2c. Medical Information	NT-D5.220				<ul style="list-style-type: none"> ✓ Verify that a preliminary review of the donor Medical information was conducted. (May be in the form of a donor work-up sheet or a donor referral.)
2d. Medical Records	NT-D4.220				<ul style="list-style-type: none"> ✓ Verify that relevant medical records or a summary of relevant medical records is available for Director/designee review.
2e. Blood Testing	NT-D5.230				<ul style="list-style-type: none"> ✓ If laboratory testing is performed, verify testing results for applicable tests, such as: <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 • anti-HTLV-II • Syphilis • Other

Donor Chart Number(s): _____

Required Document	AATB Standards	Yes	No	N/A	Required Document Content (Check yes, no, n/a upon review and verification)
3a. Donor Acquisition	NT-C1.100 NT-D6.500				Is donor acquisition documentation present and complete?
3b. Acquisition Records	NT-D6.500				<ul style="list-style-type: none"> ✓ Verify that acquisition records contain: <ul style="list-style-type: none"> • Original location of NAM • Name and address of the NADO • Date, time, and staff involved in NAM acquisition • Donor name, age, and gender • Description of the NAM acquired
3c. Donor Identity	NT-D6.120				<ul style="list-style-type: none"> ✓ Verify donor identity ✓ Source of donor verification
3d. Post-Acquisition	NT-J1.110				<ul style="list-style-type: none"> ✓ Verify post-recovery records final disposition <ul style="list-style-type: none"> • Date of final disposition • Name and address of educator/researcher who receives the NAM • Name and address of individual facilitating the final disposition • Type and quantity of NAM disposed of • Method of final disposition
3e. Sharing of Records	NT-L1.100				<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
4a. Certified Death Certificate (if applicable)	NT-D5.220				<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?
4b. Cause of Death	NT-D4.220				<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