

2nd Edition

Standards

for Non-Transplant Anatomical Donation

AATB

American Association of Tissue Banks

***STANDARDS FOR NON-TRANSPLANT
ANATOMICAL DONATION***

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2nd Edition

Online Publication Date: 11/01/17
Implementation Date: The 2nd Edition becomes effective on May 1, 2018.

These *Standards* are reviewed periodically and revised. The reader is advised to ensure that the most recent version is available for use. Updates are posted on the AATB Web site: www.aatb.org.

**Library of Congress Control Number: 2011960977
Printed in the United States of America**

About the cover: Scanning electron micrograph of freeze-dried, decellularized cancellous bone, taken with a Carl Zeiss Sigma FESEM, magnification 99x. Colorization has been used to accentuate the porous structure of the bone. Used with permission from the owner, Scott Bible, at Wright Medical, Memphis, Tennessee.

AMERICAN ASSOCIATION OF TISSUE BANKS

STANDARDS FOR NON-TRANSPLANT ANATOMICAL DONATION

INTRODUCTION

Advancements in education and/or research rely on the support and generosity of *anatomical* donation to help meet scientific and healthcare missions. These *anatomical* donations need guidelines and *Standards* to enable a donor's end of life contribution to have the desired humanitarian affect through appropriate and ethical practices. The body, or parts of the body, *may* be donated or gifted to institutions of higher education, or wishes facilitated by state anatomical boards, or non-profit or for-profit, free-standing anatomic donation organizations unless prohibited by state law. *Non-Transplant Anatomical Donation (NTAD)* is in the form of whole body donation or donations of specific tissues or organs such as the brain. *NTAD* can occur after recovery of organs and/or tissue for transplant, or when donation for transplantation is not an option. Donation for transplant shall take precedence over *NTAD*.

In 1984, the American Association of Tissue Banks (AATB) pioneered the development of professional standards for tissue intended for transplantation by publishing the *Standards for Tissue Banking*. This second edition of AATB's *Standards for Non-Transplant Anatomical Donation (Standards)* is intended to assist professionals in this parallel field and to support public trust in donation. Entities that participate in *NTAD* are entrusted with responsibility through the entire process – from *authorization* through *final disposition*.

These *Standards* reflect the collective expertise and conscientious efforts of tissue bank and *Non-Transplant Anatomical Donation Organization (NADO)* professionals to provide a comprehensive foundation for the conduct of these activities. The *Standards* will be reviewed and revised periodically by the AATB Standards Committee to incorporate scientific and technological advances and changes in standards of practice. The Standards Committee receives input from appropriate standing councils and committees and/or ad hoc groups, as well as other subject matter experts, as needed. All recommendations are subject to approval by the AATB Board of Governors.

The *Standards for Tissue Banking* has been considered, where applicable, in the formulation of these *Standards*. A glossary of terms is provided to describe terms as used in this context. Words that are defined in NT-A2.000 Definitions of Terms appear in *italics* (e.g., *audit*).

Of utmost concern is to maintain transparency and the public's trust in all donation opportunities. In crafting these *non-transplant Standards*, the attempt was made for terminology to be distinguishable between transplant and *non-transplant* terms.

For purposes of these *Standards*, the term "Non-Transplant Anatomic Donation Organization (NADO)" is used to distinguish this type of institution from a tissue bank that handles tissue for transplant. However, regardless of intended use of the donation, both institutions are recognized as tissue banks under the Uniform Anatomical Gift Act and a number of state laws and regulations. If a state requires or utilizes particular terminology, such terms can be expressed and referenced in operating procedures. Use of the

term, “NADO,” can be defined in procedures as a type of “tissue bank,” however, the “tissue bank” term is reserved for use only in the *Standards for Tissue Banking* and does not appear in these *Standards*.

These *Standards* establish requirements and provide guidance for, *authorization, acquisition, traceability, transport, donor acceptability assessment, preparation, packaging, labeling, storage, release, evaluating intended use as well as the venue appropriateness, distribution, and final disposition of Non-Transplant Anatomical Material (NAM)*. Record keeping for *NAM*, expectations for *quality assurance*, and operational and administrative *NADO* requirements are also part of these *Standards*.

Accreditation by the AATB is strongly encouraged and is based on *verified* compliance with these *Standards* and the Accreditation Policies. Use of the words “*shall*” or “*must*” in *Standards* indicates that compliance is mandatory, whereas use of the words “*should*” or “*may*” indicate recommended compliance. If an accredited *NADO*, or one seeking accreditation, does not comply with any mandatory standard, a written rationale that sufficiently demonstrates equivalency is required. Details regarding the process to request a variance from *Standards* are specified in Appendix I.

Reference materials appearing after the Appendices are provided with these *Standards* for information purposes only.

Note: Establishments that use the human body, tissues and/or cells solely for non-clinical scientific research or educational purposes, are not required to comply with Food and Drug Administration requirements at 21 CFR Part 1271 (see § 1271.15).

**STANDARDS FOR NON-TRANSPLANT ANATOMICAL DONATION
FOR EDUCATION AND/OR RESEARCH**

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