

# American Association of Tissue Banks

## *STANDARDS FOR TISSUE BANKING*

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by American Association of Tissue Banks

[14](#)<sup>th</sup> Edition

*(with amendments)*

*DISCLAIMER: Spacing and other content may differ in this “with amendments” version when compared to the final version of the 14<sup>th</sup> edition. Pages are not numbered in this version and it was collated from a number of development files. Amendments are shown using a ~~striketrough~~ for deleted or moved text and new text is shown as underlined blue font. This version is provided only as a general guide to changes. The final published version of the 14<sup>th</sup> edition must be used.*

*Do not rely on this version for compliance.*

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**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: <http://www.aatb.org/AATB-Standards-for-Tissue-Banking>.**

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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.

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# AMERICAN ASSOCIATION OF TISSUE BANKS

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## AMERICAN ASSOCIATION OF TISSUE BANKS

### *STANDARDS FOR TISSUE BANKING*

#### PREFACE

The American Association of Tissue Banks (AATB) was founded in 1976 as a voluntary, scientific, and educational not-for-profit organization to promote the exchange of information, methods, and procedures that would increase donation and provide safe, transplantable tissues of uniform high quality in quantities sufficient to meet national needs. A year later, a book of *Proceedings* [1] from the first annual meeting was published that offered a detailed overview of current tissue banking practices and described the ethics of donation and transplantation.

Between 1978 and 1981, provisional ‘*Guidelines*’ for proposed standards were drafted, discussed, adopted and published. They encompassed specific cells, tissues, and organs divided into the following categories: renal, ocular, cell and tumor tissues, bone marrow, musculoskeletal, semen and skin.

The first edition of AATB’s *Standards for Tissue Banking* was published in 1984, combining similar, general operational standards from all of these categories. This collection marked the first professional standards ever developed in the field of banking transplantable human tissues, other than ocular. An excerpt from the Scope and Purpose of this inaugural edition reads:

*“These general Standards are intended to be applicable to any and all forms of tissue banking: retrieval, storage, and distribution of human tissues for medical use. They represent the current thinking of a diversified group of experienced practitioners of tissue banking who have pooled their efforts to extract general principles and philosophies of banking operations common to all and to highlight specific considerations which pertain to certain categories of tissues.”*[2]

A voluntary accreditation program for tissue banks was launched in 1986 with inspection and accreditation based upon adherence to these *Standards*. This first publication of *Standards* was followed by the publication of a *Procedures Manual* (1986) aimed at assisting musculoskeletal, skin, and ocular tissue banks to standardize methods being used.

The following year was notable for another AATB publication titled, *Technical Manual for Tissue Banking*. It contained individual tissue-specific manuals for the banking of musculoskeletal, skin, reproductive, and (living donor) surgical bone. These manuals described step-by-step procedures to facilitate successful tissue banking operations for each tissue type. They were created by their respective councils, which had been formed within the Association.

The Technical Manual was updated with a final publication in 1992. It contained a new section for cardiovascular tissues as well as introducing the “*Protocol for Reporting an Event with the Potential for Disease Transmission*.” In time, much of the contents of these manuals were incorporated into a subsequent edition of the *Standards*, since tissue bank accreditation inspections included assessment of compliance with these technical manuals as well as *Standards*.

In the 1993 sixth edition, a section first appeared in *Standards* titled, “*Medical Facility Tissue Storage and Issuance*.” This section was directed at medical facilities to offer structural and functional

guidelines for the handling of human tissue allografts and autografts. It required the establishment of procedures and maintenance of records for tissue storage and disposition to ensure safety and traceability of tissue from receipt through clinical transfer or destruction. Other requirements included: supervision by a licensed physician (or dentist for a dental facility); monitoring of freezers and refrigerators used to store tissue; maintenance of records that included documentation of condition of tissue upon receipt; and steps involved with storage, issuance, return, disposal, recall and handling of adverse outcome reports. These standards were sent to the College of American Pathologists (CAP) as well as The Joint Commission on Accreditation of Hospitals resulting in inclusion of similar tissue handling requirements in their standards and checklists in 1993 and 1996 respectively.

By the seventh edition (1996), the AATB *Standards* had grown from 21 pages to a book of 108 pages. It included new sections, such as: Records Management; Release and Transfer of Tissues; General Operations (i.e., procedure manual, staff training/competency, safety practices, and facilities/equipment requirements); and, Quality Assurance and Quality Control. The application of a quality systems approach to all tissue banking operations, and the establishment and maintenance of a quality program became required in *Standards*. Additions to the *Standards* resembled concepts related to good manufacturing practices (GMPs), which had been adopted by a handful of AATB-accredited tissue banks that were processors of cryopreserved allograft heart valves. At that time, this group of cardiovascular tissue processors was mired in an investigational device exemption (IDE) application with the Food & Drug Administration (FDA). This resulted from FDA's unforeseen and surprising designation of these tissue banks as a "manufacturer of a replacement heart valve" [3], or better known as a Class III medical device manufacturer, the strictest device classification.

The 10th edition was published in 2002 and was the first edition to be numbered. The 11<sup>th</sup> edition in 2006 was the first to provide the *Standards* on a CD-ROM and the style of the publication changed dramatically. The cover was modernized and the publication size expanded from a 6" x 9" booklet to an 8.5" x 11" notebook with a durable, coiled spine, which allowed the book to lie flat when opened. Three-hole punches along the spine provided an option to maintain the book in a binder and the capability to insert printable updates when issued to the *Standards*. Frequent revisions became commonplace during modern times and the format changes increased user satisfaction so this publication style remains.

Similar to the 12th edition (2008), the 13th edition of *Standards* ~~includes~~ included a number of guidance documents developed by the Association's constituency to fill gaps and complement specific standards. For ease of reference regarding expected compliance, the current version of the AATB's Accreditation Policies for Transplant Tissue Banks ~~is~~ was also included. ~~in this new edition.~~

The 14<sup>th</sup> edition (2016) of *Standards* includes three new appendices. To clarify expectations for compliance, three documents previously referred to as "AATB Guidance Documents" each became incorporated as a separate appendix to the *Standards*. Where their title previously included reference as a "Guidance Document," the title was changed to reflect they are "Requirements". Therefore, the following appendices are unambiguous and compliance is mandatory:

- Appendix III Tissue Donor Physical Assessment Form Requirements (formerly AATB Guidance Document No. 1, v2 Tissue Donor Physical Assessment Form, 6-27-05)
- Appendix IV Prevention of Contamination and Cross-contamination at Recovery: Practices & Culture Results Requirements (formerly AATB Guidance Document No. 2, v2 Prevention of Contamination and Cross-contamination at Recovery: Practices & Culture Results, 6-29-07)



- [Appendix V Recovery Partner Audit Tool Requirements \(formerly AATB Guidance Document No. 6, Recovery Partner Audit Tool, 9-1-11\)](#)

[The 14<sup>th</sup> edition is the first to be published online but the printed book continues to also be available for purchase. Notice of updates to the 14<sup>th</sup> edition was provided via publication of two documents; one shows additions and deletions made throughout \[4\], and another provides a descriptive overview \[5\].](#)

From the inception of the AATB in 1976 to the present, the passionate dedication of numerous, knowledgeable tissue banking professionals has led to improvements to a variety of published guidelines, manuals, and standards. Their willingness to share experiences and best practices, to educate each other, and their ability to be forward-thinking regarding application of a quality culture to tissue banking operations, has led the way to maintaining a template (the *Standards*) that continues to be referenced not only by tissue banks, but also by end-user healthcare facilities, other standards- setting associations, and regulators worldwide. Global cooperation and the sharing of information among tissue banking professionals continues today, the same spirit that led to the formation of the AATB and the development of these *Standards*.

Scott A. Brubaker, CTBS

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#### References:

- [1] Sell KW, Perry VP, Vincent MM, *Proceedings of the 1977 Annual Meeting*, American Association of Tissue Banks, Rockville, MD, 1978
- [2] *Standards for Tissue Banking*, American Association of Tissue Banks (AATB), 1984, Arlington, Virginia
- [3] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, “Requirement for Pre-market Approval; Replacement Heart Valve Allograft”, 6/26/91
- [4] [14th Edition of AATB’s Standards for Tissue Banking with Amendments.pdf](#)
- [5] [Overview and Updates – 14th Edition of AATB’s Standards for Tissue Banking.pdf](#)

## AMERICAN ASSOCIATION OF TISSUE BANKS

### STANDARDS FOR TISSUE BANKING

#### INTRODUCTION

Progress in medical science and cell biology has resulted in the *transplantation* of human cells and *tissue* from one human into another, enhancing the quality of life by restoring form and function and facilitating reproduction. For more than ~~50~~ 60 years, society has recognized the medical and humanitarian value of donating and *transplanting* organs and *tissues*. The universal significance of this is made apparent by the enactment of legislation based on the Uniform Anatomical Gift Act. The American Association of Tissue Banks (AATB), through its constituency, is committed to providing stewardship for gifts of donated human *tissue* and promoting the public trust in donation and *transplantation*.

A mission of the AATB is to establish and promulgate standards to provide *tissue banks* with performance requirements intended to prevent disease transmission and support *quality* measures that assist clinical performance of *transplanted tissue*. Furthermore, the AATB fosters education and research, and promotes *quality* and *safety* in cell and *tissue banking* and *transplantation*.

The AATB's "*Standards for Tissue Banking*" (*Standards*) reflect the collective expertise and conscientious efforts of tissue bank professionals to provide a comprehensive foundation for the guidance of *tissue banking* activities. The *Standards* are reviewed periodically and revised by the AATB Standards Committee to incorporate scientific and technological advancements. The Standards Committee receives input from the Association's Councils (Accredited Tissue Bank, Physicians', Processing and Distribution, Quality, Recovery and Donor ~~Eligibility~~ *Suitability*, and Reproductive) and appropriate standing committees and/or ad hoc task forces, as needed. All revisions are subject to approval by the AATB Board of Governors.

In the *Standards*, terms and related words with a similar meaning that are defined in A2.000 Definitions of Terms appear in italics [e.g., *verification* (*verify*, *verified*)]. Additionally, the *Standards* contain appendices that *must* be followed.

These *Standards* establish performance requirements for *informed consent* or *authorization*, donor ~~*Suitability*~~ *eligibility* assessment through donor screening and testing, as well as for the *recovery*, *processing*, *storage*, *packaging*, *labeling*, and *distribution* of transplantable human ~~cells~~ *tissue*. ~~musculoskeletal, skin, reproductive, cardiac, and vascular tissue.~~ The *Standards* are intended to be applied to *tissue bank* functions that relate to *quality*, staff, *donors*, and *tissue*, but do not encompass the clinical use of ~~cells and tissue~~. In addition, unless otherwise stated, these *Standards* apply only to *tissue* intended for clinical use or *transplantation* to recipients (including use in assisted reproductive technology procedures).

Accreditation by the AATB is based on *verified* compliance with these *Standards* and the Accreditation Policies for Transplant Tissue Banks and is strongly encouraged. Use of the words "*shall*" or "*must*" in *Standards* indicate mandatory compliance, whereas use of the words "*should*" and "*may*" indicate recommended compliance. If an accredited *tissue bank*, 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. ~~Accreditation by the AATB is based on verified compliance with these *Standards* and is strongly encouraged.~~

The format of this edition of *Standards* is that of general requirements applicable to all *tissue* with subsections delineating *donor* and *tissue* standards for:

(A) *autologous tissue*,

(BT) *birth tissue*,

(C) *cardiac tissue*,

(CT) *cellular tissue*,

(DM) *dura mater*,

(LD) *living donors*,

(MS) *musculoskeletal tissue*,

(OA) *osteoarticular graft*,

(R) *reproductive cells and tissue*,

(S) *skin*,

(SB) *living donor surgical bone for allogeneic use*, and

(V) *vascular tissue*.

- For all *living donors*, (LD) standards apply, then tissue-specific standards apply.
- For *tissue* that falls into one or more of these categories, both the general and *tissue*-specific standards apply ~~and they should be referenced~~.
- When a particular numbered item appears in both the general section and *tissue*-specific subsection, both requirements shall apply unless noted otherwise.
- The *tissue*-specific standard is not a replacement for the general standard for that item, except as noted.
- For *tissue* not included in these categories (e.g., parathyroid *tissue*, ~~islet cells~~, ~~neural tissue~~), the general standards shall apply.
- ~~In addition, unless otherwise stated, these Standards apply only to tissue intended for clinical use or transplantation to Recipients (including use in Assisted Reproductive Technology procedures). Accreditation will be based upon compliance with these Standards and the Accreditation Policies for Transplant Tissue Banks.~~

~~In the Standards, words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these Standards.~~

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## SECTION E PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE

### E1.000 RECEIPT OF TISSUE AT PROCESSING/STORAGE FACILITY

- E1.100 Tissue Identification
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  - [E2.420](#) Containers
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- [E2.500](#) Processing Methods
  - [E2.510](#) Temperature Limits
  - [E2.520](#) Time Limits for [Pre-processing](#), Processing and Preservation Phases
  - [E2.530](#) Prevention of Matrix Deterioration
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  - ~~E1.061 Techniques~~
  - [E2.710](#) Lyophilization
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- [E3.400](#) Expiration Date/Storage Period
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- ~~E1.031 (C, V) Documentation of Tissue Condition~~
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## SECTION F ~~RELEASE AND TRANSFER OF~~ TISSUE RELEASE

### F1.000 TISSUE RELEASE—~~GENERAL REVIEW REQUIREMENTS~~

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### H1.000 DISTRIBUTION AND DISPENSING—~~GENERAL~~

- H1.100 Tissue Distribution and Dispensing Restrictions
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- H1.200 ~~Transfer of~~ [Distributing](#) Tissue to Other Tissue Banks/Dispensing Services
  - [H1.210 Consignment Inventory Management](#)
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- H3.[200](#) Integrity
- H3.[300](#) Tissue Storage Environment
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- H3.[500](#) Quality Control [of Reusable Shipping Packages](#)
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- K1.100 Basic Elements
- K1.200 Qualification, Verification, and Validation Requirements
  - [K1.210 Validation Methods](#)
  - K1.220 (C, V) [Packaging Qualification and Transport/Shipping](#) ~~Validation of Shipping Containers~~
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- K2.300 Microbiological Tissue Cultures
  - K2.310 Pre-Sterilization/Pre-Disinfection Cultures
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- K2.400 ~~(C, V)~~ Testing for Residues
- K2.500 Other Quality Control Procedures
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## K3.000 MICROBIOLOGIC TESTING

- ~~K3.100 Transport Medium~~
- ~~K3.200 Selection of Growth Medium~~
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## K4.000 INVESTIGATIONS

- K4.100 Errors and Accidents
- K4.200 Complaints
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- K7.100 Authorized Access
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## [SECTION L TISSUE DISPENSING SERVICES](#)

### L1.000 TISSUE DISPENSING SERVICES—~~GENERAL~~

- L1.100 Responsibilities

### L2.000 STORAGE

- L2.100 General
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### L3.000 ~~RELEASE~~ [DISPENSING, FURTHER DISTRIBUTION AND DISPOSAL](#)

- L3.100 Dispensing
- L3.200 ~~Release to Another Tissue Dispensing Service or Tissue Distribution Intermediary~~  
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L4.000 RECORDS

L4.100 Tissue Receipt Records

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[SECTION M TISSUE DISTRIBUTION INTERMEDIARIES](#)

M1.000 TISSUE DISTRIBUTION INTERMEDIARIES—GENERAL

M2.000 STORAGE

M2.100 General

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M4.100 Tissue Distribution Restrictions

M4.200 [Distribution to Another Tissue Distribution Intermediary](#) ~~Transfer of Tissue Other-~~  
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M4.300 Requests for Donor Status and Tissue Processing Information

[M5.000 CONSIGNMENT INVENTORY MANAGEMENT](#)

[M6.000](#) PACKAGING AND SHIPPING

~~M4.100 Tissue Storage Environment~~

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M6.200 Validation and Packaging Expiration

[M6.300](#) Transportation

[M6.310 Domestic Shipments](#)

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[M7.000](#) RETURN OF TISSUE

[M8.000](#) [FIELD](#) CORRECTIONS AND REMOVALS — GENERAL

M8.100 [Field](#) Correction and Removal Records

[M9.000](#) RECORDS

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Appendix I: REQUEST FOR VARIANCE FROM STANDARDS

Appendix II: CRITERIA FOR PREVENTING TRANSMISSION OF RCDADs (Relevant  
Communicable Disease Agents and Diseases) THROUGH TRANSPLANTATION OF  
HUMAN TISSUE

Appendix III: TISSUE DONOR PHYSICAL ASSESSMENT FORM REQUIREMENTS

Appendix IV: PREVENTION OF CONTAMINATION AND CROSS-CONTAMINATION AT RECOVERY: PRACTICES & CULTURE RESULTS REQUIREMENTS

Appendix V: RECOVERY PARTNER AUDIT TOOL REQUIREMENTS *(to be made available during 2016)*

## SECTION A GENERAL INFORMATION

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### A1.000 ACCREDITATION

AATB accredited *tissue banks* must comply with these *Standards*, the Accreditation Policies for Transplant Tissue Banks, as well as all applicable laws and regulations.

#### A1.100 Failure to Comply with Standards

Failure of an accredited *tissue bank* to comply with *Standards* and the Accreditation Policies for Transplant Tissue Banks, ~~as judged by a majority of the AATB's Board of Governors, shall be reviewed and corrective action will be considered~~ in accordance with the [Accreditation Policies for Transplant Tissue Banks](#) bylaws. Accreditation may be [denied, rescinded, suspended, or withdrawn](#) upon a determination by the Board of Governors that significant ~~non-compliance~~ [noncompliance](#), such as repeated violations, one or more egregious violations, uncorrected violations, or deliberate falsehoods, have occurred.

#### A1.200 Requesting a Variance to Standards

*Tissue banks* wishing to implement a *variance* from current *Standards* must provide the following information to the AATB ~~Chief Policy Officer~~ [Senior Vice President of Policy](#) by using the Request for Variance to AATB *Standards* Submission Format. The format *must* be completed in entirety and include:

- 1) A request for *variance* or modification including the particular standard number(s) that applies to the request;
- 2) Justification of the alternative *procedure(s)*, policy or process that assure(s) equivalency to the intent of *Standards*; and
- 3) Supporting information such as worksheets, *records*, data, or other information (e.g., *validation* of the protocol to be used in the proposed *variance*, including the scientific data and *quality assurance* steps).

Until the Board of Governors approves the *Variance* request, the *tissue bank* must comply with existing *Standards*. See Appendix I. [A record of the approved variance must be maintained at the requesting tissue bank as well as at any other accredited tissue bank directly affected by the approval. Evidence of approval of the request for variance must be available during an accreditation inspection.](#)

### A2.000 DEFINITIONS OF TERMS

[Words that are defined here also appear in italics throughout the \*Standards\*. Related words with a similar meaning in the form of a noun, verb, or adjective, or in the plural form or as past tense, as applicable, may also be italicized, but are not defined separately. Examples include “\*recovery/recover/recovered\*,” “\*establish/established/establishment \(of\)\*,” “\*verification/verify/verified\*,” “\*validation/validate/validated\*” and “\*distribution/distribute/distributed\*.”](#)

Unless otherwise defined in the *tissue*-specific standards or otherwise used in another context in these

*Standards*, the following terms *shall* be defined as follows:

~~AAMI~~—Association for the Advancement of Medical Instrumentation

**ACCIDENT** – Any occurrence, not associated with a *deviation* from standard operating *procedures* (SOPs), standards, or applicable laws and regulations, during *donor* screening or testing, or *tissue recovery*, ~~or collection~~ or acquisition, *processing*, *quarantining*, *labeling*, *storage*, *distribution*, or *dispensing* that *may* affect the performance, biocompatibility, or freedom from transmissible pathogens of the *tissue* or the ability to *trace tissue* to the *donor*.

**ACQUISITION (BT)** – The point after delivery at which *tissue* is under the control of the *tissue bank*.

**ADEQUATE INFORMATION** – Information sufficient for the *donor*, the *authorizing person* or the *living donor* to make a voluntary decision regarding the gift of *tissues* for *transplantation*, therapy, research and/or education. The parameters of what constitutes *adequate information* must include “Core Elements” contained in ~~Standard~~ D2.400 or D3.400, and such additional information as the *donor*, *authorizing person*, or *living donor* requests or which the *donation coordinator* reasonably believes the *donor*, *authorizing person* or *living donor* *should* know. When the *donor* is *authorizing* the gift of *tissue*, publicly available information concerning the scope and use of the gift *shall* be deemed *adequate information*.

**ADVERSE OUTCOME** – An undesirable effect or untoward complication in a *recipient* consequent to or reasonably related to *tissue transplantation*.

**ALLOGENEIC** – Used as an adjective to modify donation, *tissue*, *donor* or *recipient* when *transplantation* is intended for a genetically different person.

**ALLOGRAFT** – *Tissue* intended for *transplantation* into ~~another individual of the same species~~ a genetically different person.

**ANONYMOUS DONOR (R)** – A *reproductive donor* of ~~cells or~~ *tissue* whose identity is unknown to the *recipient* (R).

~~ANSI~~—American National Standards Institute

~~AORN~~—Association of periOperative Registered Nurses

**AORTOILIAC GRAFT (C)** - The distal segment of the abdominal aorta including the bifurcation and proximal segments of both the left and right common iliac arteries.

~~ART~~—Assisted Reproductive Technology—All clinical treatments and laboratory procedures that include the handling of both human oocytes and sperm, or embryos, with the intent of establishing a pregnancy.

**ARTERIAL GRAFT (V)** – A segment of peripheral artery that is recovered, processed and *preserved*.

**ARTIFICIAL INSEMINATION (R)** – The placement of *semen* within the reproductive tract of a *recipient* (R).

**ASEPTIC PROCESSING** – The *processing* of *tissue* using ~~methods to prevent, restrict or minimize contamination with microorganisms from the environment, processing personnel, and/or equipment.~~ aseptic techniques where *tissue*, *containers* and/or *devices* are handled in a controlled environment in

[which the air supply, materials, equipment and personnel are regulated to prevent microbial contamination of \*tissue\*.](#)

**ASEPTIC RECOVERY** – The *recovery* of *tissue* using methods that restrict or minimize contamination with *microorganisms* from the *donor*, environment, *recovery* personnel, and/or equipment.

**ASRM** — American Society for Reproductive Medicine

**ASSISTED REPRODUCTIVE TECHNOLOGY PROCEDURE (R)** – A medical *procedure* intended to result in conception, including, but not limited to, therapeutic insemination, in-vitro fertilization (including intracytoplasmic sperm injection), and *gamete* intrafallopian *transfer*.

**ASYSTOLE** – The reference time for cardiac death. A documented pronounced time of death is used as *asystole* when life-saving *procedures* have been attempted and there were signs of, or documentation of, recent life (e.g., witnessed event, agonal respirations, pulseless electrical activity). If a death was not witnessed, *asystole must* be determined by the last time known alive. *Asystole* will be ‘cross clamp time’ if the *tissue donor* was also a solid organ *donor*.

**AUDIT** – A documented review of *procedures*, *records*, personnel functions, equipment, materials, facilities, and/or suppliers to evaluate adherence to the written *SOPM*, standards, applicable laws and regulations.

**AUDIT TRAIL** - [A process that captures details such as additions, deletions, or alterations of information in an electronic \*record\* without obliterating the original \*record\*. An \*audit\* trail facilitates the reconstruction of the course of such details relating to the electronic \*record\*. \(FDA Guidance for Industry, Computerized Systems Used in Clinical Investigations, May 2007\)](#)

**AUTHORIZATION** – Permission given after *adequate information* concerning the donation, *recovery* and use of *tissues* is conveyed.

**AUTHORIZING PERSON** – Upon the death of the *donor*, the person, other than the *donor*, authorized by law to make an anatomical gift.

**AUTOGRAFT (A)** – *Tissue* intended for implantation, *transplantation* or infusion into the ~~individual~~ [living donor](#) from whom ~~they were~~ [it was](#) recovered.

**AUTOLOGOUS** – Used as an adjective to modify donation, *tissue*, *donor* or *recipient* when [donation is intended only from him/herself and](#) *transplantation* ~~to only one’s self is involved~~ [is intended only to him/herself](#).

**BATCH** – A specific quantity of *tissue* ~~that is intended to have a uniform character and quality, within specific limits, which is~~ produced according to a single *processing* protocol during the same *processing* cycle, ~~precluding mixing of tissue from two or more donors.~~

**BIOBURDEN** – The number of contaminating organisms found on a given amount of material.

**BIRTH TISSUE (BT)** – [gestational \*tissue\* donated at the time of delivery of a living newborn. This includes placenta, Wharton’s jelly, amniotic fluid, chorionic membrane, amniotic membrane, placental/chorionic disc, umbilical veins, and umbilical cord tissue.](#)

**BLOOD COMPONENT** – Any part of a single-donor unit of blood separated by physical or



mechanical means.

**CARDIAC TISSUE (C)** – Tissue type that includes, but is not limited to, valved conduits, non-valved conduits, aortoiliac grafts, and patch grafts.

~~**CBER** – Center for Biologics Evaluation and Research~~

~~**CDC** – Centers for Disease Control and Prevention~~

**CELLULAR TISSUE (CT)** – viable cells that are *autologous* or *allogeneic*, committed or uncommitted, and non-expanded.

**CERTIFIED COPY** – Relating to a death certificate, an original, authenticated form produced by a governing authority.

~~**CFR** – Code of Federal Regulations. Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC~~

**CLAIM** – Any written or oral communication alleging the *quality*, durability, reliability, infectious disease risk, or performance of *tissue*.

~~**CLEAN ROOM** – A room in which the concentration of airborne particles is monitored and controlled to defined specification limits.~~

**CLIENT DEPOSITOR (R)** – A person, ~~or persons, who store(s) reproductive cells or~~ who consents to collection and/or storage of reproductive tissues for ~~future use in artificial insemination or assisted reproductive technology procedures~~ for themselves or a sexually intimate partner; not considered a *reproductive tissue donor*.

**COLD ISCHEMIC TIME (C)** – The time interval from subjecting cardiac *tissue* to cold rinse (or transport) solution at *recovery* to the beginning of *disinfection*.

**COLD ISCHEMIC TIME (V)** – The time interval from subjecting *vascular tissue* to transport solution and wet ice temperatures at *recovery* to the beginning of *disinfection*.

**COLLECTION (R)** – The acquisition of ~~semen or retrieval of oocytes~~ reproductive tissue from a *donor* or *client depositor* by surgical or non-surgical *procedures*.

**COLLOID** – A protein or polysaccharide solution that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment such as albumin, dextran, hetastarch, or certain blood components, such as plasma and platelets.

**COMPLAINT** – Any written or oral communication concerning dissatisfaction with the identity, *quality*, *packaging*, durability, reliability, *safety*, effectiveness, or performance of *tissue*.

**COMPETENCY** – The ability of an employee to acceptably perform tasks for which he/she has been trained.

**COMPETENCY ASSESSMENT** – The evaluation of the ability of an employee to acceptably perform tasks for which he/she has been trained.

**CONSIGNEE** – Any *tissue bank*, *tissue distribution intermediary*, *tissue dispensing service*, or *end-user*

(whether individual, agency, institution, or organization) that receives *finished tissue*.

**CONTAINER** – An enclosure for one finished unit of *transplantable tissue*.

**CONTRACT SERVICES** – Those functions pertaining to the *recovery*, screening, testing, *processing*, *storage*, and/or *distribution* of human *tissue* that another establishment agrees to perform ~~for a tissue establishment~~.

**CONTROLLED AREAS** – Restricted work areas of low microbial and particulate content in which non-sterile materials are prepared.

**CORRECTION** – Related to conformity, remedial action to eliminate a detected *nonconformity*.

**CORRECTIVE ACTION** – Action to eliminate the cause and prevent recurrence of a *nonconformity* or other undesirable situation; may be performed in conjunction with *preventive action(s)*.

**CRITICAL** – Classification of a supply, reagent, material, instrument or equipment that can affect the *quality* and/or *safety* of *tissue*.

**CRITICAL AREAS** – Restricted work areas where cells, tissue, containers and/or closures are exposed to the environment.

**CROSS-CONTAMINATION** – The transfer of infectious agents from one tissue to an other tissue from either the same *donor* or a different donor ~~from one donor's tissue to another donor's tissue~~.

**CRYOPRESERVED** – ~~Tissue~~ Frozen with the addition of, or in a solution containing, a *cryoprotectant* agent such as glycerol or dimethylsulfoxide.

**CRYOPROTECTANT** – An additive that serves to minimize osmotic imbalances that occur with the progression of freezing fronts through a substance, and is intended to limit the amount of cell damage caused by cell shrinkage and intracellular ice formation.

**CRYSTALLOID** – A balanced salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume, such as saline solution, Ringer's lactate solution, or 5 percent dextrose in water, or total parenteral nutrition (TPN).

**DECONTAMINATION** - Cleaning the environment, facilities, and/or surfaces (sanitation), or instruments, supplies, and equipment (sanitization), with intent to remove or reduce pathogenic microbes.

**DEHYDRATION** – The removal of water from *tissue*. For example, dehydration methods may include chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a dehydrator.

**DESICCATION** – The removal of water from *tissue*. For example, desiccation methods may include chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a desiccator.

**DEVIATION** – An event that is a departure from a *procedure* or normal practice.

**DIRECTED DONOR (R)** – A ~~reproductive cell or~~ *tissue donor* who is known to the *recipient* (R) but is not ~~her~~ the recipient's (R) sexually intimate partner.

**DISINFECTANT** – ~~An agent that reduces the number of viable cellular microorganisms.~~ An agent (e.g., heat or a chemical) capable of reducing the number of viable *microorganisms*. A disinfectant might

[not kill spores. Use of antimicrobials in tissue processing is included here.](#)

**DISINFECTION** – A process that reduces the number of viable ~~cellular~~ *microorganisms on tissue*, but does *may* not necessarily destroy all microbial forms, such as spores and viruses. Use of ~~antibiotics,~~ while not normally described as disinfection, [antimicrobials in tissue processing](#) is included here.

**DISINFECTION TIME (C, V)** – The time interval between subjecting *tissue* to *disinfection* solution and transferring *tissue* to rinsing solutions in preparation for *preservation*.

**DISPENSING SERVICE** – A facility responsible for the receipt, maintenance and delivery to the ultimate user (e.g., *transplanting* surgeon, surgical center or research facility) of *tissue* for *transplantation* or research.

**DISPOSITION** – The final destination of *tissue*, including e.g., use for *transplantation*, *therapy* research, [education](#), or discard; [also, the final destination of critical supplies, reagents, materials or equipment that can affect the quality and/or safety of tissue, e.g., release for use or discard.](#)

**DISTRIBUTION** – A process that includes receipt of a request for *tissue*, selection of appropriate *finished tissue*, preparation for transport, any required inspections, and subsequent shipment and delivery of *tissue* to another *tissue bank*, *tissue distribution intermediary*, *tissue dispensing service*, or *end-user*.

**DOCUMENT OF AUTHORIZATION** – Legal *record* of the gift of *tissue*, permitting and defining the scope of the postmortem *recovery* and use of *tissues* for *transplantation*, *therapy*, research and/or education *signed* or otherwise *recorded* by the *authorizing person*, pursuant to law.

**DOCUMENT OF GIFT** – The *donor's* legal *record* of the gift of *tissue* permitting and defining the scope of the postmortem *recovery* and use of *tissues* for *transplantation*, *therapy*, research and/or education. It *must* be *signed* or otherwise *recorded* by the *donor* or person authorized under law to make a gift during the *donor's* lifetime.

**DOCUMENT OF GIFT/AUTHORIZATION** – Term used when the standard refers to both a *document of gift* and a *document of authorization* as defined above.

~~**DONATED EMBRYO** – An embryo designated for implantation into a recipient other than the oocyte donor.~~

**DONATED HUMAN TISSUE** – For the purposes of *labeling*, this is *tissue* provided for *storage* or *transplantation*, either *allogeneic* or *autologous*.

**DONATION COORDINATOR** – A *responsible person* who seeks *authorization* from an *authorizing person*, or who makes *notification* concerning donation, *recovery*, and use of the gift, or in the case of a *living donor* or *client depositor*, ~~the~~ [a responsible person who seeks informed consent from a living donor, a birth mother, or a client depositor.](#) For *authorization* purposes, this person *may* also be referred to as a “designated requestor.”

**DONOR** – A living or deceased individual whose body is the source of the *tissue*.

**DONOR SUITABILITY ELIGIBILITY ASSESSMENT** – The evaluation of all available information about a potential *donor* to determine whether the *donor* meets qualifications specified in the *SOPM* and *Standards*. [See relevant medical records.](#) ~~This includes, but is not limited to: medical, social, and sexual histories; laboratory test results; physical assessment or physical-~~

examination; and autopsy findings (if performed).

**DONOR RISK ASSESSMENT INTERVIEW (DRAI)** – A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the *donor's* relevant medical history and social behavior. For example this *may* be: the *donor*, if living; the next of kin; the nearest available relative; a member of the donor's household; other individual with an affinity relationship (e.g., caretaker, friend, significant life partner); and/or the primary treating physician. Alternatively, a *living donor may* complete a written questionnaire. The relevant social history is elicited by questions regarding certain activities or behaviors that are considered to place such an individual at increased risk for a relevant communicable disease agent or disease (RCDAD).

**DONOR REFERRAL SOURCES** – Entities such as hospitals, medical examiners, coroners and individual allied health care professionals who identify potential *tissue donors* and refer them, or their next of kin, to *tissue banks*.

**DONOR REGISTRY** – A database established in accordance with law, consisting of legally valid *documents of gift*.

**DOSIMETRIC RELEASE** – *Tissue* release based on dosimetry instead of sterility testing.

**DURA MATER (DM)** – A type of soft *tissue* that includes the pachymeninx (thick, membranous) tissue covering the brain.

**DYNAMIC** – Operational condition during *aseptic processing* where the controlled environment is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon [ISO 14644-1].

**ELECTRONIC SYSTEMS** – Computerized systems that create source documents (electronic *records*).

**EMBRYO (R)** – Pre-implantation, *reproductive tissue* resulting from the combination of oocyte and sperm.

**EMBRYO BANK** – A facility that performs cryopreservation or *storage* of embryos intended for use in creating pregnancy.

**EMBRYO CLIENT DEPOSITOR (R)** – A woman and/or man who provides *gametes* or contracts with a *gamete donor(s)* responsible for creation of an *embryo(s)* intended for *transfer (R)*.

**EMBRYO DONOR (R)** – *Embryo client depositor(s)* who choose(s) to donate his/her (their) *embryos*. Ownership of the *embryos* is transferred to a new *client depositor(s)* who was (were) not *gamete* providers.

**END-USER** – A health care practitioner who performs *transplantation procedures*.

**ENVIRONMENTAL CONTROL** – Activities performed to control the environment for the purpose of minimizing the potential for contamination or cross-contamination of tissue.

**ENVIRONMENTAL MONITORING** – Activities performed to systematically observe and record data to characterize the environment to identify conditions under which the potential may exist for contamination or cross-contamination of tissue.

**EQUIPMENT QUALIFICATION STUDIES** – Protocols designed to adequately evaluate, prior to

use, whether pieces of equipment will perform to expectations, and normally function within the required *tolerance limits*.

**ERROR** – A ~~departure~~ [deviation](#) from the *SOPM*, *Standards*, or applicable laws or regulations.

**ESTABLISH(ED)** – ~~d~~[Define](#), document and implement.

**FDA** – ~~The United States Food and Drug Administration~~

**FETAL TISSUE** – ~~Tissue recovered during embryonic or fetal stages of development.~~

**FIELD CORRECTION** – [For distributed tissue](#), the repair, modification, adjustment, *relabeling*, destruction, or inspection (including patient monitoring) ~~of distributed tissue~~ without its physical removal to some other location. Reference 21 *CFR* Part 7, 7.3(h).

**FIELD NOTIFICATION** – The provision of additional information pertaining to the *safety*, *quality*, identification, function and/or use of distributed *tissue*.

**FINISHED TISSUE** – *Tissue* that has been fully *processed*, enclosed in its final *container*, *labeled*, and released to *distribution* inventory.

**FREEZE DRIED/LYOPHILIZED** – ~~Tissue dehydrated for storage by conversion of the water content of frozen tissue to a gaseous state under vacuum that extracts moisture.~~

**GAMETE (R)** – Mature human germ cell, whether an oocyte or sperm.

**GESTATIONAL CARRIER (R)** – ~~A woman contracted by the embryo client depositor(s) for pregnancy gestation under the supervision of the embryo client depositor's(s') physician.~~

**INFORMED CONSENT** – Permission given by a *living donor* (LD) or *client depositor* who is presented with a description of the scope, use and any risks or benefits to her or him of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives her or his *informed consent* to donation *shall sign* ~~an~~ [a record of the](#) *informed consent record*.

**IN-PROCESS CONTROLS** – Any tests, samples, evaluations, monitoring, or measurements performed during *processing* or *preservation* that are designed to ~~evaluate the processing or preservation procedure of the tissue subjected to processing or preservation for~~ [ensure](#) conformance to specifications in the *SOPM*.

**IN-PROCESS MATERIAL** – Any material that is used in the *processing* of *tissue*, including, but not limited to, incoming *tissue*, water, alcohol, acid, *containers*, and closures.

**ISO** – ~~International Organization for Standardization~~

**LABEL** – Any written, printed, or graphic material used to identify *tissue*, cultures, blood specimens or other *donor* specimens.

**LABELING MATERIAL** – Any printed or written material, including *labels*, advertising, and/or accompanying information (e.g., *package insert*, brochures, and pamphlets), related to the *tissue*.

**LIVING DONOR (LD)** – ~~An individual~~ [A person](#) who consents to the *recovery* or *collection* of his

or her *tissue*, where *recovery* or *collection* is to take place while she or he is alive. For all *living donors*, (LD) standards apply, then *tissue*-specific standards apply. A *living donor* is a type of *donor* and, unless otherwise specified, standards that apply to *donors* in general apply to *living donors*.

**LOT** – *Tissue* produced from one *donor* at one time using one set of instruments and supplies. Also refers to a quantity of reagents, supplies, or *containers* that is *processed* or manufactured at one time and identified by a unique identification number.

**LYOPHILIZED/FREEZE DRIED** – *Tissue* dehydrated for *storage* by conversion of the water content of frozen *tissue* to a gaseous state under vacuum that extracts moisture.

**MANAGEMENT WITH EXECUTIVE RESPONSIBILITY** – Those senior employees of a *tissue bank* who have the authority to establish or make changes to the *tissue bank's quality policy* and *quality system*.

**MARKET WITHDRAWAL** – A *field* correction or *removal* of distributed *tissue* that involves a minor violation that would not be subject to legal action by the *FDA* or that involves no violation (e.g., normal stock rotation practices). Reference 21 *CFR* Part 7, 7.3(j).

**MAY** – Used to indicate an acceptable method that is recognized but not essential.

**MICROORGANISMS** – A microscopic organism (e.g., including bacteria and fungi); viruses, while sometimes included in this classification, are not included here.

**MUSCULOSKELETAL TISSUE (MS)** – *Tissue* type that includes, but is not limited to, bone and cartilage, and soft *tissue* such as tendon, ligament, nerve, fascia, pericardium, peritoneal membrane, adipose, and *dura mater*.

**MUST** – Used to indicate a mandatory requirement. The same as *SHALL*.

**NONCONFORMITY** - A finding that identifies non-fulfillment of an accreditation requirement, a standard, policy, process, *procedure*, or specification.

**NON-TERMINAL IRRADIATION** – Ionizing radiation used to reduce microbes prior to *processing*.

**NON-VALVED CONDUIT (C)** – A length of cardiac outflow tract (aortic or pulmonic) from which the valve structure has been removed or intentionally rendered completely non-functional.

**NOTIFICATION (OF GIFT)** – Provision and documentation of notice concerning an anatomical gift that was made by the *donor* during the *donor's* lifetime.

**OOCYTE DONOR (R)** – ~~One~~ A person who donates oocytes for use in *assisted reproductive technology procedures*. An *oocyte donor* can be further categorized as a *directed donor* or an *anonymous donor* but is not a client depositor.

**OSTEOARTICULAR GRAFT** – A ~~large~~-weight bearing *allograft* with intact articular surfaces, consisting of a joint with associated soft *tissue* and bone.

**PACKAGE** – A labeled box, carton, receptacle, or wrapper containing tissue and may contain one or more *containers* and accompanying *labeling materials*.

**PACKAGE INSERT** – The written material accompanying an ~~tissue~~ *allograft* or *autograft* bearing



further information about the *tissue*, directions for use, and any applicable warnings.

**PATCH GRAFT (C)** – A segment of cardiac *allograft* conduit to be used in cardiovascular repair, replacement, construction, or reconstruction.

**PERFUSION SOLUTION (V)** – A room temperature, sterile isotonic solution such as tissue culture media or PlasmaLyte® utilized to gently perfuse veins at *recovery*. This solution *may* also contain an antithrombotic agent (i.e., sodium heparin).

**PERFUSION TIME (V)** – The time interval from *asystole* to subjecting the *vascular tissue* to *perfusion solution*.

**PHYSICAL ASSESSMENT** – A recent ante-mortem or postmortem documented evaluation of a deceased *donor's* body that can identify evidence of: high-risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, trauma to the potential *recovery* sites.

**PHYSICAL EXAMINATION** – A recent documented evaluation of a *living donor's* body to determine whether there is evidence of high risk behavior and that determines overall general health of the *donor*. After a *donor risk assessment interview* is completed and if any history is suspect, the physical examination *should* also encompass a directed examination (of a body part or region).

**PLASMA DILUTION** – A decrease in the concentration of the *donor's* plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids, e.g., *colloid(s)* and/or *crystalloid(s)*.

**POLICIES AND PROCEDURES MANUAL** – See Standard Operating Procedures Manual (SOPM).

**POOLING** – The physical contact or mixing of *tissue* from two or more *donors* in a single receptacle.

**PRE-STERILIZATION/PRE-DISINFECTION CULTURE** - A culture of *tissue* obtained prior to ~~exposing the tissue~~ exposure to antibiotics, *disinfecting* chemicals, or *sterilizing* agents.

**PRESERVATION** – The use of chemical agents, alterations in environmental conditions or other means during *processing* to prevent or retard biological or physical deterioration of *tissue*.

**PREVENTIVE ACTION** – Action to eliminate the cause of a potential *nonconformity* or other undesirable situation; may be performed in conjunction with *corrective action(s)*.

**PROCEDURE** – A series of steps, which when followed, is designed to result in a specific outcome.

**PROCESS CONTROLS** – A system of checks and balances incorporated into *standard operating procedures* involving critical operations to prevent errors.

**PROCESS VALIDATION STUDIES** – ~~The process of demonstrating~~ Establishing by objective evidence that a ~~specific process or procedure will consistently produces~~ expected a results meeting ~~within~~ predetermined specifications.

**PROCESSING** – Any activity performed on *tissue* other than *donor* screening, *donor* testing, *tissue recovery*, ~~and collection,~~ or acquisition functions, ~~storage,~~ or distribution or dispensing. It includes but is not limited to disinfecting, sterilizing, packaging, labeling, and testing tissue.

**PROFICIENCY TESTING** – ~~An~~ The evaluation of an individual laboratory's performance against

~~pre-established criteria by means of inter-laboratory comparisons methods and test results that assesses the quality of standard operating procedures, equipment, supplies, and reagents, as well as the skill of the personnel performing the testing.~~ [\(Adapted from ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing\)](#)

**QUALIFICATION** – The process of establishing confidence that equipment, [materials](#), reagents, and ancillary systems are capable of consistently ~~operating~~ [performing](#) within established limits and tolerances. Process performance qualification is intended to establish confidence that the process is effective and reproducible.

**QUALITY** – The conformance of *tissue* or a process ~~with~~ [to](#) pre-established specifications or standards.

**QUALITY AGREEMENT** – [an agreement that establishes the \*quality\* specifications or standards that must be met for defined activities and delineates responsibilities of each entity involved. It may be a separate document or included as part of a written agreement/contract.](#)

**QUALITY ASSURANCE (QA) PROGRAM** – The policies and environment required to meet standards of *quality* and safety, and [to](#) provide confidence that the processes and *tissue* consistently conform to *quality* requirements.

**QUALITY CONTROL (QC)** – Specific tests defined by the *QA program* to be performed to monitor *recovery, processing, preservation and storage, tissue quality*, and test accuracy. These *may* include but are not limited to, performance evaluations, inspection, testing, and controls used to determine the accuracy and reliability of the *tissue bank's* equipment and operational *procedures*, as well as the monitoring of supplies, reagents, equipment, and facilities.

**QUALITY POLICY** – The overall intentions and direction of an organization with respect to *quality*, as established by *management with executive responsibility*.

**QUALITY SYSTEM** – The organizational structure, responsibilities, *procedures*, processes, and resources for implementing quality management.

**QUARANTINE** – The identification of ~~human~~ *tissue* as not suitable for *transplantation*, including ~~human~~ *tissue* that has not yet been characterized as being suitable for *transplantation*. Quarantine includes the *storage* of such *tissue* in an area clearly identified for such use, or other *procedures*, such as automated designation, to prevent the release of this *tissue* for *transplantation*. [This also applies to reagents, supplies, materials and equipment pending approval for use or that has been determined to be nonconforming.](#)

**RECALL** – A [field](#) *correction* or *removal* of *distributed tissue* initiated to reduce a risk to health posed by the *tissue* or to remedy a violation of regulatory requirements that *may* present a risk to health.

**RECIPIENT** – A person into whom *tissue* is *transplanted*.

**RECIPIENT (R)** – A woman undergoing an *assisted reproductive technology procedure*. [A recipient \(R\) can be an intended parent, a gestational carrier, or a gestational surrogate.](#)

**RECORD** - Information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

**RECOVERY** – Obtaining *tissue* [other than reproductive tissue](#) from a *donor* that is intended for use in



human *transplantation*, therapy, research or education.

**RECOVERY SITE** – The immediate area or room where a *tissue recovery* takes place (e.g., dedicated *tissue recovery suite* [site](#), healthcare facility operating room, autopsy suite).

**RELEVANT MEDICAL RECORDS** – A collection of documents including a current ~~donor risk assessment interview, a physical assessment/physical examination~~ [donor risk assessment interview, a physical assessment/physical examination](#) of the donor, laboratory test results (in addition to results of testing for required communicable disease agents), relevant *donor records*, existing coroner and autopsy reports, [a certified copy or verified copy of the death certificate \(when applicable\)](#), as well as information obtained from any source or *records* which may pertain to *donor suitability eligibility* regarding high risk behaviors, and clinical signs and symptoms for any relevant communicable disease agent or disease (RCDAD), and/or treatments related to medical conditions suggestive of such risk.

**REMOVAL** – The physical removal of *distributed tissue* from its point of use to some other location for repair, modification, adjustment, *relabeling*, destruction, or inspection. Reference 21 *CFR* Part 806, 806.2(i).

**REPRODUCTIVE TISSUE (R)** – Any ~~cells and/or~~ *tissue* from the reproductive tract intended for use in *assisted reproductive technology procedures*. This includes, but is not limited to: oocytes, ovarian *tissue*, *embryos*, *semen*, spermatozoa, spermatids, testicular *tissue*, and epididymal *tissue*.

**REPRODUCTIVE TISSUE BANK (R)** – A *tissue bank* that *collects, processes, stores, and/or distributes* human reproductive *tissue* for use in *assisted reproductive technology procedures*.

**RESOLUTION** – Adjustment, clarification, and/or correction of practices and/or *procedures* that results in compliance with the *SOPM* and/or standards.

**RESPONSIBLE PERSON** – A person who is authorized to perform designated functions for which he or she is trained and qualified.

**SAFETY** – A *quality* of *tissue* indicating handling according to standards and substantial freedom from the potential for harmful effects to *recipients*.

**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).~~ [A facility operated or owned by the \*tissue bank\* and located in a physically separate location from its primary address, and where any tissue banking activities occur or where any tissue banking services are provided.](#)

**SEMEN (R)** – The fluid of man's reproductive system consisting of spermatozoa and secretions of accessory glands.

**SEMEN BANK (R)** – ~~A tissue bank that collects, processes, stores, and/or distributes semen for use in artificial insemination or assisted reproductive technology procedures.~~

**SEMEN DONOR (R)** – ~~One~~ [A man](#) who donates *semen* for use in artificial insemination or *assisted reproductive technology procedures* where the *recipient* is not a sexually intimate partner. A *semen donor* can be further categorized as a *directed donor* or an *anonymous donor* [but is not a client depositor](#).

**SERIES OF STANDARDS** – [A group of standards related to a particular topic presented as a capitalized heading \(e.g., B2.000\) followed by indented subsections \(e.g., B2.100, B2.120, B2.121\). The heading and everything indented under it are considered part of the series.](#)

**SERVICES TO DONOR FAMILIES** – A defined policy or support program describing *tissue* donation follow-up offered to the *authorizing person* (or party). This *may* include written communications regarding: potential uses of *tissue*; *recovery* outcome information; bereavement information and support; provision of a copy of the *document of gift/authorization*; and/or guidance describing how to contact the *tissue bank* if any questions arise regarding the donation. Frequency of follow-up and program maintenance is at the discretion of the *tissue bank*, however, periodic evaluation of services is required.

**SHALL** – Used to indicate a mandatory standard, same as *MUST*.

**SHOULD** – Used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there *may* be effective alternatives.

**SIGN (SIGNED, SIGNATURE)** – A *record* is signed when it has been authenticated or adopted by the signer by means in writing, or an electronic signature, symbol, sound, process or *recording* pursuant to applicable law.

**SKIN (S)** - [A membranous soft \*tissue\* type that includes, but is not limited to epidermis and dermis.](#)

**SKIN PREP** - The application of antiseptic ~~agent~~[solution](#) to decontaminate the *skin*. This is a continuous process that is performed without delay between steps; it does not include shaving hair, although this can be done if preferred. The manufacturer's written recommendations *must* be followed, including that the antiseptic ~~agent~~[solution](#) *should* remain in place for the ~~full~~ [recommended contact](#) time [and be allowed to air dry completely before the surgical drapes are placed.](#)

**STANDARD OPERATING PROCEDURES MANUAL (SOPM)** – A group of standard operating *procedures* (SOPs) detailing the specific policies of a *tissue bank* and the *procedures* used by the staff/personnel to carry out the functions of the *tissue bank*.

**STANDARDS** – AATB *Standards for Tissue Banking*

**STATIC** - [At-rest condition during \*aseptic processing\* where the controlled environment is complete with equipment installed and operating in a manner agreed upon, but with no personnel present \[ISO 14644-1\].](#)

**STERILE** – [For \*tissue\*, the absence of detectable, viable, \*microorganisms\* \(refer to ANSI/AAMI ST67:2003](#)~~2003~~[2011\).](#) [For reagents, supplies, materials and equipment, free from viable \*microorganisms\*.](#)

**STERILITY ASSURANCE LEVEL (SAL)** – The probability of a single viable *microorganism* occurring on a product after *sterilization* (refer to ANSI/AAMI ST67:2003).

**STERILIZATION** – A validated process used to render *tissue* free from viable *microorganisms* (refer to ANSI/AAMI ST67:2003) including spores.

**STOCK RECOVERY** – ~~A correction or removal~~ [Retrieval](#) of *tissue* that has not left the direct control of the *tissue bank* (manufacturer), i.e., the *tissue* is located on the premises owned, or under the control of, the *tissue bank* (manufacturer), and no portion of the affected *tissue* has been released for use. Reference 21 CFR Part 7, 7.3(k).

**STORAGE** – The maintenance of *tissue* for future use.

**STRUCTURAL SUPPORT** – Those *tissue* grafts that contribute biomechanical strength to a surgical construct.

**SUMMARY OF RECORDS** – A condensed version of the *donor* testing and ~~suitability~~ eligibility determination *records*. This can be combined with the *package insert*.

**SURGICAL BONE (SB)** – Any bone from a *living donor* for *allogeneic* use such as a femoral head removed during surgery.

**TERMINAL STERILIZATION** – A validated process whereby *tissue* within its final sterile barrier system (e.g., ~~primary package~~, container) is *sterilized* (refer to ANSI/AAMI ST67:2003 2011).

**THIRD PARTY RECORDS** – *Records* produced by an entity not involved in *tissue recovery*, acquisition, or *donor* screening. Examples of third party *records* include: hospital medical *records*; emergency medical services *records*; coroner/medical examiner *records*; prenatal records, and police reports.

**TISSUE** – A functional group of cells. The term is used collectively in *Standards* to indicate both cells and *tissue*.

**TISSUE BANK** – An entity that provides or engages in one or more services involving *tissue* from living or deceased ~~individuals~~ persons for *transplantation* purposes. These services include obtaining authorization and/or informed consent, assessing *donor* ~~suitability~~ eligibility, *recovery*, collection, acquisition, processing, storage, labeling, distribution and dispensing of *tissue*.

**TISSUE DISPENSING SERVICE** – Any entity that receives, *stores*, and provides *tissue* directly to an *end-user* for *transplantation*. *Tissue dispensing services* may or may not be *tissue banks*, depending on what other functions they perform.

**TISSUE DISTRIBUTION INTERMEDIARY** – An intermediary agent who acquires and *stores tissue* for further *distribution* and performs no other *tissue banking* functions.

**TISSUE IDENTIFICATION NUMBER** – Any unique combination of letters, numbers, and/or symbols assigned to *tissue* and linked to a *donor*, from which the complete history of the recovery, collection or acquisition, processing, packaging, quarantine, labeling, storage, distribution and dispensing of *tissue* can be traced. Identical *tissue processed* under the criteria defined in “*lot*” may be assigned the same *tissue identification number*.

**TOLERANCE LIMITS** – The limits that define a range of acceptable values that are established for each testing *procedure* which, when exceeded, require the implementation of *corrective actions* designed to produce results within the acceptable range in future tests.

**TOTAL ISCHEMIC TIME (C, V)** – The time interval from *asystole* to subjecting *tissue* to *disinfection* solution. This is the sum of *warm ischemic time* and *cold ischemic time*.

**TRACEABILITY** – The ability to locate *tissue* during any step of its donation, *recovery*, ~~or collection~~, or acquisition, *processing*, testing, *storage*, *distribution* or *disposition*. It implies the capacity to identify the medical facility receiving the *tissue* and, at the medical facility, the ability to identify the *recipient*.

**TRANSFER (R)** – The placement of human *reproductive tissue* into a human *recipient* (R).

**TRANSPLANTATION** – The transfer of [an allograft or autograft](#) ~~tissue~~ to a *recipient*.

**TRANSPORT MEDIUM** – Any microbiological medium capable of maintaining cellular viability during the transport of a culture from field to laboratory.

**VALIDATION** – ~~The process of establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce the predetermined outcome.~~ [Confirmation through the provision of documented objective evidence that predefined specifications have been fulfilled and can be consistently reproduced.](#)

**VALVED CONDUIT (C)** – An *allograft* heart valve with an attached length of cardiac outflow tract (aortic or pulmonic).

**VARIANCE** – A departure from *Standards* that is pre-approved by the AATB Board of Governors prior to implementation.

**VASCULAR TISSUE (V)** – [Tissue type that includes, but is not limited to arterial grafts and vein grafts.](#)

**VEIN GRAFT (V)** – A segment of vein that is *recovered, processed* and *preserved*.

**VERIFICATION** – The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

**VERIFIED COPY** - [A copy of a death certificate without the raised seal but issued by an authorizing agency.](#)

**VETERINARY USE** – Treatment of a condition or disease in a non-human animal.

**WARM ISCHEMIC TIME (C)** – The time interval from *asystole* to subjecting cardiac *tissue* to cold rinse (or transport) solution at *recovery*.

**WARM ISCHEMIC TIME (V)** – The time interval from *asystole* to subjecting *vascular tissue* to transport solution and *wet ice temperatures* at *recovery*.

**WET ICE TEMPERATURES** – Temperatures ranging from above freezing (0°C) to 10°C.

**WITNESS** – An individual who signifies in writing, or in electronically *recorded* format, that he or she has observed the execution or verbal authorization of the *document of gift/authorization* or *informed consent*. The *witness*' signification *must* be contemporaneous with execution and the *witness must* be identified by name, address and/or such other contact information as is relevant and feasible. A *witness should* not be an employee or agent of the *tissue bank* or requesting entity.

### **[A3.000 ACRONYMS AND ABBREVIATIONS](#)**

[The following acronyms and abbreviations are used in \*Standards\*:](#)

**AAMI** – Association for the Advancement of Medical Instrumentation

**[AATB](#)** – [American Association of Tissue Banks](#)

**ANSI** – American National Standards Institute

**AORN** – Association of periOperative Registered Nurses

**ASQ** – American Society for Quality

**ASTM** – ASTM International

**CAP** – College of American Pathologists

**CBER** – Center for Biologics Evaluation and Research

**CDC** – Centers for Disease Control and Prevention

**CFR** – Code of Federal Regulations. Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC

**e.g.** – *exempli gratia*; for example, such as; the list is not finite

**FDA** – The United States Food and Drug Administration

**i.e.** – *id est*; that is; indicates a finite list

**ISO** – International Organization for Standardization

**USP** – United States Pharmacopeia

## SECTION B

### GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

#### **B1.000 GENERAL INSTITUTIONAL REQUIREMENTS**

##### **B1.100 Purpose, Institutional Identity, and Affiliations**

The purpose of the *tissue bank* shall be clearly formulated and documented. The *tissue bank* shall state whether it is a freestanding entity or part of an institution.

##### **B1.200 Governing Body**

The *tissue bank* shall have a Governing Body that *may* consist of a Board of Trustees, Board of Governors, Board of Directors or a designated responsible individual in whom policy-making authority resides, unless otherwise provided by the institution of which it is a part. A Board shall consist of individuals from various professions. This Board or designated individual shall determine the scope of activities to be pursued by the *tissue bank*.

The Governing Body shall designate one or more senior employees as *management with executive responsibility*. Issues of liability, ethical considerations, fiduciary responsibility, and compliance with applicable laws and regulations, these *Standards*, and the *tissue bank's* SOPM shall be the responsibility of the Governing Body and *management with executive responsibility*.

##### **B1.300 Medical/Scientific Support**

A *tissue bank* should establish and maintain a mechanism to access medical, technical, and scientific advice as needed. Decisions shall be documented.

##### **B1.400 Satellite Facilities**

*Satellite facilities* shall be operated in accordance with the *tissue bank's* SOPM.

##### **~~B1.500 Multi-Facility Tissue Banking~~**

~~When two or more *Tissue Banks* participate jointly in *Recovery, Processing, Storage, and/or Distribution*, the relationship and responsibilities of each shall be delineated in writing and that documentation shall be maintained at each participating bank or facility. Any records necessary to demonstrate compliance shall be readily accessible to the distributing tissue bank. Compliance with *Standards* by all parties shall be required and documented.~~

~~If an AATB-accredited *bank* obtains from and *processes tissue* for a *tissue bank* not accredited by the AATB that is located outside of the United States (U.S.), the requirement for compliance with *Standards* does not apply to the foreign *tissue bank* if the *processed tissues* will not be *distributed* within, or to, the U.S. All cells and *tissues* imported from entities that do not follow AATB *Standards* shall be appropriately *quarantined* throughout import, *storage, processing, and export*. The AATB-accredited *tissue bank* must verify that the foreign *tissue bank* not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform~~

~~(e.g., consent/authorization, donor screening, recovery, donor testing). Additionally the tissue bank not accredited by the AATB should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's "Safety of Human Cells, Tissues and Organs for Transplantation Regulations;" the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the World Health Organization's "Aide Mémoires for Human Cells and Tissues for Transplantation."~~

#### **B1.510 B1.500 Written Agreements/Contracts**

Each *tissue bank* shall have written agreements or contracts with all other individuals or organizations that perform or for whom they perform *tissue banking activities or services such as, but not limited to: authorization, informed consent, donor screening, donor acceptability, tissue recovery, processing or distribution* for their organization.

- 1) donor referral;
- 2) authorization;
- 3) informed consent;
- 4) donor eligibility assessment;
- 5) recovery, collection, and/or acquisition;
- 6) post-delivery functions;
- 7) laboratory services (see exception at B1.600);
- 8) testing services;
- 9) processing;
- 10) storage;
- 11) tissue release;
- 12) distribution; and/or
- 13) consignment.

For additional controls regarding testing services and other services performed by others, see the series of standards at K1.300.

Written agreements or contracts *shall* indicate 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. The *tissue bank shall* maintain a copy of each such agreement, which *shall* be made available for review if requested by AATB inspectors. Compliance with Standards by all parties shall be required and documented in a quality agreement. The following examples provide a few of these expectations:

- 1) A *tissue bank* that *recovers* tissue that is *processed* and/or *distributed* by another *tissue bank* shall be responsible for being in compliance with these *Standards* for all operations it performs. This includes, but is not limited to, the requirement to have a Medical Director



(see B2.220-Responsibilities), to follow applicable standards in Section D and Appendix II, and to share records (see [D4.300](#) ~~D4.500~~ Information Sharing, and K1.100 ~~Basic Elements of a Quality Assurance Program~~). A tissue bank that recovers tissue is not required to audit its contracted tissue bank processor(s).

(BT) There shall be a written agreement/contract with the entity that performs post-delivery functions and/or acquisition on behalf of the tissue bank; or, if there is no written agreement or contract, there must be an attestation record from a responsible person that post-delivery protocols and procedures are followed.

- 2) A tissue bank that processes tissue recovered and/or distributed by another tissue bank shall be responsible for being in compliance with these Standards for all operations it performs. The tissue processing organization must bear the burden of proof, and document in writing, that operations performed by other organizations prior to the receipt of tissue for processing were performed in a manner consistent with these Standards as well as the processing tissue bank's requirements.
- 3) A tissue bank that distributes tissue recovered and/or processed by other tissue banks shall be responsible for being in compliance with AATB Standards for all operations it performs. The distributor must also bear the burden of proof, and document in writing, that operations performed by other organizations prior to its receipt of tissue for distribution were performed in a manner consistent with AATB Standards. Any records necessary to demonstrate compliance shall be readily accessible to the distributing tissue bank.
- 4) A tissue bank that determines donor suitability ~~eligibility~~ shall develop and maintain policies and procedures that clearly describe donor records they deem relevant to their operations. Agreements must address how this information is to be communicated in a timely fashion and clearly define expectations and responsibilities of the appropriate entities.
- 5) A tissue bank that provides another tissue bank with critical supplies, reagents, materials, and/or equipment shall develop and maintain policies and procedures that clearly describe responsibilities for notification of changes and recalls, and both entities should report problems (e.g., defects). The tissue bank providing supplies containing labels is responsible for archiving and notification responsibilities described at ~~standard~~ G2.330.
- 6) A tissue bank that distributes tissue for transplantation shall restrict distribution to entities described in Standards (see H1.100). If tissue is provided to a tissue distribution intermediary, the tissue distribution intermediary shall meet the requirements of Section M of these Standards.

If an AATB-accredited tissue bank obtains from and processes tissue for a tissue bank not accredited by the AATB that is located outside of the United States (U.S.), the requirement for compliance with Standards does not apply to the foreign tissue bank if the processed tissues will not be distributed within, or to, the U.S. All cells and tissues imported from entities that do not follow AATB Standards shall be appropriately quarantined throughout import, storage, processing, and export. The AATB-accredited tissue bank must verify that the foreign tissue bank not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., informed consent/authorization, donor screening ~~eligibility assessment~~, recovery, acquisition, donor testing). Additionally the tissue bank not accredited by the AATB should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's "Safety of Human Cells, Tissues and Organs for Transplantation Regulations;" the Directive (and



Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the World Health Organization's "Aide Mémoires for Human Cells and Tissues for Transplantation."

#### **~~B1.520~~ B1.510 On-site Inspections**

(Refers to any AATB accreditation/~~re-accreditation inspections~~ inspection.)

A *tissue bank* ~~that has any of its activities or services performed by another entity~~ will be inspected and accredited ~~only~~ for the specific activity(ies) or service(s) that ~~the tissue bank itself~~ it performs. However, if the tissue bank participates jointly with other entities that provide tissue banking activities or services on their behalf, the accredited tissue bank is responsible for providing evidence of compliance to these Standards for all tissue banking activities or services performed by other entities on its behalf.

#### **~~B1.521~~ B1.520 Inspections/Audits of Other Facilities**

(Refers to inspections/*audits* that an accredited *tissue bank* must perform for activities/services rendered by another entity.)

Before an entity performs any activity/service under contract, agreement or other arrangement, the accredited *tissue bank* must ensure that the entity will comply with applicable *Standards*, laws and regulations. Thereafter, the accredited *tissue bank* is responsible for *verifying*, at least biennially, that the activity(ies) or service(s) has/have been performed in conformance with applicable *Standards*, laws and regulations. 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 for Transplant Tissue Banks).~~ 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 are in compliance with these *Standards*, the written agreement/contract, and applicable laws and regulations. The inspection/*audit* plan, policies, and *procedures* *shall* be specified in the *SOPM*.

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*, the agreement/contract and applicable laws and regulations. This itemization of the systems reviewed *shall* be provided to AATB on-site inspectors upon request. For an *audit* tool and ~~guidelines~~ requirements to be used for a partner performing *recovery* services, refer to ~~Guidance Document No. 6~~ Appendix V.

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 *tissue 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.

#### **B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease**

## Testing

*Tissue banks* that contract for laboratory services [for donor infectious disease testing](#) shall retain in their *records* the name and address of the contracted facility and documentation of the inclusive dates of the contract period. Proof of current laboratory licensure and accreditation *must* be maintained. [Additionally, all requirements in the series of standards at K1.300 shall apply.](#) *Tissue banks* that obtain [donor infectious disease testing](#) results from non-contracted laboratory services (e.g., other *tissue banks*, organ procurement organizations) shall maintain the name, address, licensing and accreditation information for each laboratory from which test results are obtained for the purpose of *donor suitability eligibility* or *tissue-qualification suitability* assessments. Appropriate *management with executive responsibility* shall [ensure a responsible person understands](#) ~~be responsible for understanding~~ the principles of bacteriological and/or infectious disease test *procedures* employed by a laboratory as well as the interpretation of results. *Records* of [infectious disease](#) laboratory results used to [assess donor eligibility](#) ~~determine final release~~ shall become part of the *donor or Processing record*.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, test kit licensing/approval, and test run record retention.

The *tissue bank* must ensure (and maintain documentation of activities obtained by either paper *audit* or on-site *audit*) that a laboratory performing *donor* infectious disease testing for the *tissue bank* is:

- 1) registered with the FDA as a tissue establishment and lists ‘testing’ as a function;
- 2) using the appropriate FDA-licensed, approved, or cleared *donor* screening tests;
- 3) following manufacturers’ instructions for these tests;
- 4) certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services;
- 5) retaining *donor* infectious disease test run *records* for ten years; and
- 6) aware of the requirement of the *tissue bank* to comply with ~~Standard D4.240. Archived Samples.~~

~~The *tissue bank* must ensure (and maintain documentation of activities obtained by either paper audit or on-site audit) that the contracted laboratory(ies) performing microbiology testing related to determination of tissue suitability is:~~

- ~~1) registered with the FDA as a tissue establishment and lists ‘processing’ as a function;~~
- ~~2) following applicable manufacturers’ instructions for these tests; and~~
- ~~3) retaining tissue microbiological identification records for ten years.~~

## **B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK**

### **B2.100 Management Responsibility**

### **B2.110 Quality Policy**

*Management with executive responsibility shall ensure the establishment of the tissue bank's policy and objectives for, and commitment to, quality, and shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.*

### **B2.120 Organization**

Each *tissue bank shall establish and maintain an adequate organizational structure to ensure that ~~donors are consented/authorized, screened and tested, and tissue is recovered and collected, or processed, stored, packaged, labeled, and distributed~~ all tissue banking activities or services comply in accordance with the requirements of these Standards.*

### **B2.121 Responsibilities and Authority**

Each *tissue bank shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks in accordance with these Standards. The tissue bank shall ensure that responsibilities and authorities are defined, documented and communicated within the tissue bank.*

### **B2.122 Resources**

The *tissue bank shall have sufficient resources, including the assignment of trained personnel, for management, performance of work, and assessment activities to meet the requirements of these Standards.*

### **B2.123 Management Representative**

*Management with executive responsibility shall appoint a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained. The management representative shall periodically report on the performance of the quality system to management with executive responsibility for their review.*

### **B2.130 Management Review**

*Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of these Standards and the tissue bank's established quality policy and objectives. The dates and results of quality system reviews shall be documented.*

### **B2.140 Technical Policies and Procedures**

Technical policies and *procedures* utilized in the operation of the *tissue bank must be established and maintained. The tissue bank may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided that the tissue bank has verified that the procedures are consistent with, and at least as*

stringent as, the requirements of these *Standards* and appropriate for operations.

### **B2.150 Quality Assurance Program**

A *quality assurance (QA) program* shall be established and maintained to ensure that the entire operation is in conformity with the *tissue bank's SOPM*, [these Standards](#), and applicable laws and regulations. A documented annual internal review or *audit* to ensure compliance *must* be performed. ~~The Self-assessment Tool/Audit Report (STAR) must be completed annually and documented on a form provided by, or pre-approved by, the AATB Director of Accreditation (refer to the AATB Accreditation Policies for Transplant Tissue Banks).~~

## **B2.200 Medical Director**

### **B2.210 Qualifications**

The *tissue bank* shall have a Medical Director who maintains a valid ~~state~~ [medical license](#) from any state [or U.S. territory](#) (or for international members, the physician *must* maintain an equivalent medical license). He/she *should* have training and experience in evaluating and determining ~~donor suitability~~ [eligibility](#) particularly with regard to infectious diseases, or use a Medical Advisory Committee or consultants to assist in those areas.

### **B2.220 Responsibilities**

[The Medical Director shall establish, review and approve all policies and procedures of a medical nature. See J1.300, J1.400, J1.600.](#)

### **B2.221 Donor ~~Suitability~~ [Eligibility](#) Criteria**

The Medical Director *shall* ~~be responsible for establish~~ [establishing](#) ~~donor suitability~~ [eligibility](#) criteria. [See the series of standards at D4.000 and Appendix II.](#)

[The tissue bank's donor eligibility criteria may be adopted from criteria used by another organization, provided that the Medical Director has verified the criteria are consistent with, and at least as stringent as, the requirements of these Standards and applicable laws and regulations.](#)

[When a tissue bank is responsible for determining donor eligibility, as well as evaluate and determine each donor's acceptability. Prior to the release of tissue for transplantation, the Medical Director, or licensed physician designee, shall make a determination regarding the acceptability \[eligibility\]\(#\) of each donor based on a comparison with predetermined donor criteria as established in the SOPM. This determination must occur prior to the release of tissue for transplantation. See Section F.](#) by the Medical Director and in accordance with these *Standards*. The Medical Director shall review and approve all the SOPs of a medical nature prior to implementation.

### **B2.222 Adverse Outcomes**

The Medical Director *shall* establish policies and *procedures* regarding *adverse outcomes*. [See K4.300.](#) ~~and shall require that all potential Adverse Outcomes are investigated and documented. Corrective actions shall also be~~

~~documented. All final summary reports shall be reviewed and approved by the Medical Director. Adverse Outcomes must be reported as required by applicable laws or regulations.~~

#### **B2.223 ~~Confirmed~~ Positive Infectious Disease Test Results**

The Medical Director *shall* be responsible for notifying appropriate parties of ~~confirmed~~ the availability of positive infectious disease test results, and for reporting positive test results when required, in accordance with ~~Standard D4.356~~ D4.232.

### **B2.300 Technical Staff**

#### **B2.310 Qualifications**

Staff *must* possess the educational background, experience, and training sufficient to assure assigned tasks ~~are~~ will be performed in accordance with the *tissue bank's* established *procedures*. ~~Donor authorization, informed consent for living donors, donor screening and testing, recovery, collection, processing, packaging, labeling, storage, and distribution, shall be performed by trained personnel.~~ Staff training *shall* be documented in individual employee training files.

#### **B2.320 Responsibilities**

Staff *shall* be responsible for implementation of policies and *procedures* as established by the *tissue bank*. Duties of each staff member *shall* be described in written job descriptions. Staff *must* demonstrate *competency* in the operations to which they are assigned.

### **B2.400 Quality Assurance Program**

#### **B2.410 Staff Qualifications**

A designated individual, generally familiar with, but not having performed, the specific work being reviewed, *shall* be responsible for each ~~Quality Assurance~~ quality review.

#### **B2.420 Staff Responsibilities**

*Quality assurance program* personnel *shall* have responsibility for assuring compliance with the *SOPM* regulatory requirements. The individual responsible for the ~~Quality Assurance~~ quality review *shall* have the responsibility and authority to approve or reject *tissue*, as well as discontinue *processing* and/or release of *tissue* when *deviations* from *SOPM* warrants. *Quality assurance* personnel *shall* be responsible for managing *audits*.

## SECTION C RECORDS MANAGEMENT

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### C1.000 RECORDS MANAGEMENT

#### C1.100 General

Each *tissue bank* shall develop a *donor* record management system that will allow the detailed documentation of the *tissue banking* process(es) for which ~~the bank~~ [it](#) is responsible. Documentation *must* be made concurrent with each significant step and *must* include, but not be limited to:

- [1\) information from the donor referral source;](#)
- [2\) donor eligibility assessment information;](#)
- ~~4~~[3\) record of informed consent, or document of gift/authorization;](#)
- ~~2~~[4\) donor ~~suitability~~ physical assessment or physical examination,](#) and donor identification;
- ~~3~~[5\) tissue recovery or collection, transport, and processing;](#)
- ~~4~~[6\) quarantine and infectious disease testing;](#)
- ~~5~~[7\) in-process testing;](#)
- ~~6~~[8\) record review;](#)
- ~~7~~[9\) tissue labeling, storage, release, and distribution;](#)
- ~~8~~[10\) quality control; and](#)
- ~~9~~[11\) services to donor families.](#)

~~Records shall be created beginning with donor screening documentation.~~ Such *records* shall indicate the responsible party(ies) and *must* delineate the dates, times, and locations of subsequent *procedures* as well as the individuals performing them in order to facilitate *traceability*. The *records* shall be considered confidential and *shall* be kept in a location with controlled access; precautions for their safety and security *should* be evident.

- (A) *Records* shall include, at a minimum, *donor* identification, and the date and time of *recovery*.
- (R) Names of donors *shall* be encoded; only designated personnel *shall* have the authority to link the *donor's* name to the identification code. No *records* shall exist which link the *anonymous donor* [by name](#) to the *recipient* ~~by name~~.

#### C1.110 Required Processing Documentation

Results of laboratory tests used to determine final release of *tissue* for *transplantation*

(e.g., *sterility* testing and testing for residual water, ethylene oxide, residual calcium) shall be maintained by the *tissue bank* that determines the suitability of the *allograft* for distribution (“distributor”). All other *processing records* shall be available ~~at~~ to the tissue bank within a reasonable amount of time ~~or available by facsimile, within the same workday.~~

#### **C1.120 Electronic Records**

If *records* are maintained electronically, there shall be ~~a~~ an electronic system in place to ensure that data integrity of the electronic *records* is maintained, and that information is retrievable, and able to be printed as a hard copy. Compliance with K7.000 is expected.

#### **C1.200 Availability for Inspection**

Tissue banking *records* shall be readily accessible for inspection by authorized personnel from accreditation programs, and regulatory agencies, ~~and tissue banks involved with the bank in multi-facility tissue banking.~~ Access to *donor* identity and medical, social, travel, and sexual behavior histories shall be restricted to *tissue bank* staff with a need for access and to inspectors from accreditation programs and regulatory agencies. Should *records* be maintained electronically, there *must* be a system in place to retrieve information, and print a hard copy for review during inspection or for a period as required by applicable laws and regulations.

#### **C1.300 Retention**

Records of the *informed consent*, *documents of gift/authorization*, and *records* pertaining to donor suitability eligibility, *recovery*, *collection*, acquisition, *processing*, *storage*, date of *distribution*, *QA*, and identity of person/entity to whom *distributed*, shall be retained at least 10 years beyond the date of *distribution*, date of *transplantation* (if known), date of *disposition*, or date of expiration of the *tissue* (whichever is latest) or longer if required by applicable laws and regulations. *Records* shall be maintained in a manner to preserve their completeness and accuracy over time. *Donor suitability eligibility* *records* of *dura mater* donors shall be retained indefinitely. *Tissue banks* that have their *tissues* processed by another agency *must* assure that *processing* and *QC records* are retained for at least ten years.

- (R) The *reproductive tissue bank* should maintain current *donor* and *client depositor* addresses until *tissues* are used or destroyed.

#### **C1.400 Traceability**

A *tissue bank's* *records* management system shall identify *tissue* by use of a unique identifier. Each subsequent entity involved in the process of *recovery*, *collection* or acquisition through *tissue* dispensing shall be required to correlate its *donor* identifier with the *donor* identifier of the entity from which it acquired the *tissue*. *Records* shall also indicate the dates and the identities of the staff involved in each significant step of the operation from the time of *recovery*, *collection* or acquisition through final *disposition* of the *tissue*.

Laboratory and *QC* specimens related to a *donor of tissue* shall also be *traceable* to the *donor*. *Records* shall indicate which specimens were used for testing and shall also permit *tracing* from the *donor* to the specimen and from the specimen to the *donor*.

Whenever an accredited *tissue bank* consigns *tissue* to a non-accredited entity, the accredited tissue bank shall:



- 1) require the non-accredited entity to comply with the requirements of this section; and
- 2) impose the requirements of this section on all subsequent *consignees*, up to and including the *tissue dispensing service*.

### **C1.500 Revisions**

Revisions to paper records shall be made with a single line drawn through the altered text. The revision shall be initialed and dated by the individual making the revision. Additions to a completed record shall be initialed and dated by the individual making the additions.

Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision. See K7.000.

### **C2.000 CONSTRUCTION OF RECORDS**

~~Before tissue is released or transferred, the~~ Relevant medical records must be reviewed by the responsible person(s) at each tissue bank involved with recovery, collection or acquisition, or the determination of donor eligibility. The content of records that originate or are sourced from outside of a tissue bank (i.e., *third party records*) is not under control of the *tissue bank*. The information in these records is considered the best available information. Records that are produced by *tissue bank* staff must be complete, indelible, legible and accurate. Records must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

*Tissue banks shall not utilize documentation related to informed consent/authorization or donor risk assessment interviews that are obtained by unauthorized parties. Authorized parties must be identified in agreements and personnel performing these functions shall be qualified, trained, and competent.*

- (A) *Autologous tissue records shall be maintained either in a separate log, or, if incorporated into general records, in such a manner that the autologous tissue may not be released for non-autologous use.*
- (C) *Records additionally shall include the following information:*
  - 1) ABO/Rh, if available;
  - 2) date/time of *asystole*;
  - 3) date/time of *recovery* of the heart (time when subjected to cold rinse solution);
  - 4) date/time of subjection of cardiac ~~Allograft~~ tissue to *disinfection* solution;
  - 5) start and stop times when *tissue* was subjected to *disinfection* solution; and
  - 6) date/time
    - (a) when *preservation* began; and
    - (b) when placed in final *container*.



(V) *Records additionally shall include the following information:*

- 1) ABO/Rh, if available;
- 2) [date/time](#) of *asystole*;
- 3) [date/time](#) *vascular tissues* subjected to *perfusion solution*;
- 4) [date/time](#) *vascular tissues* placed in transport solution and subjected to *wet ice temperatures*;
- 5) [date/time](#) of subsection of *vascular tissue* to *disinfection* solution;
- 6) [start](#) and stop times when *tissue* was subjected to *disinfection* solution; and
- 7) [date/time](#) (a) when *preservation* began and (b) when placed in final *container*.

### **C3.000 DONOR RECORDS TO BE MAINTAINED**

*Tissue Banks shall maintain records of their activities in accordance with these Standards.*

- (R) *Donor records shall include documentation of informed consent, relevant medical records, results of all laboratory screening tests, and outcome of prior assisted reproductive technology procedures (if known) including number of successful pregnancies and any reports that would affect the donor's acceptability [eligibility](#). Records shall also include the following personal attributes [of the donor such as](#): height, weight, eye color, hair color, complexion, racial group, and [/or](#) body type.*

### **~~C4.000 PROCESSING RECORDS TO BE MAINTAINED BY OTHERS~~**

~~*Tissue banks that have their tissues processed by another entity must assure that the processing and QC records of that entity are retained for a period as required by applicable laws and regulations.*~~

**SECTION D**  
**ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR**  
**SCREENING, AND TISSUE RECOVERY, AND COLLECTION, AND ACQUISITION**

Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.

**D1.000 GENERAL POLICIES FOR TISSUE RECOVERY OR COLLECTION-  
ORGANIZATIONS**

In addition to the requirements at the *series of standards* at B1.500 ~~Multi-Facility Tissue Banking~~, all referral arrangements with organ procurement organizations, *donor referral sources* and other *tissue banks* shall be documented.

(LD) Except for a *reproductive tissue bank*, written *procedures* for interacting with operating room staff, the patient's physician, or other sources/facilities shall be established.

~~(R) Procedures for accepting tissue collected from a *Client Depositor*, and for recruiting, accepting or excluding potential reproductive tissue donors, shall be established by the Medical Director.~~

**D1.100 Monetary Compensation or Other Valuable Consideration ~~to Donors~~**

Monetary compensation or other valuable consideration, including goods or services, shall not be offered to a *donor*, *authorizing person*, the *donor's* estate, or any other third party acting on behalf of the donor, except in the following instances:

1) the *tissue bank* may reimburse responsible third parties for costs directly associated with a donation; or

2) the *tissue bank* may reimburse *living donors* for costs associated with an acceptable donation, including compensation for restoration of lost earnings when directly attributable to donation, if and as authorized by law.

(R) The *reproductive tissue bank* may provide monetary compensation to *donors* of *reproductive tissue* if the compensation is compliant with ~~current ASRM Guidelines for Gamete and Embryo Donation~~ professional standards of practice.

*Donors* or their families *should* not be responsible for any expenses related to the *recovery* of *allogeneic tissue*.

**D1.200 Tissue for Research**

Facilities providing *tissue* for research and other non-transplantation purposes shall develop detailed relevant specific policies and procedures. Informed consent or authorization for research and/or education shall be obtained. See the *series of standards* at D2.000 and D3.000.

**D1.210 Written Requests**

All requests for human *tissue* intended for research use shall be submitted in writing. The request shall indicate the type of *tissue* requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the *tissue*.

### **D1.220 Review and Approval**

Tissue requests for research purposes shall be reviewed and approved based on legal, ethical, and technical considerations defined in the SOPM.

## **D2.000 AUTHORIZATION**

### **D2.100 Requirements**

*Authorization to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a donor or authorizing person in accordance with applicable anatomical gift acts and other laws or regulations. This authorization shall be expressed in a document of gift/authorization, the original or a copy of which shall be maintained in the donor's record at the tissue bank responsible for recovery, as well as in the donor's record at the tissue bank whose Medical Director is responsible for the donor suitability eligibility determination. In the case of an electronic or voice recorded document of gift/authorization, the original recording should be maintained in reproducible form.*

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful authorization for donation of tissues for transplantation, therapy, research, or education.

### **D2.200 Conditions**

*Adequate information concerning the donation and recovery of tissue shall be presented in a language in which the authorizing person is conversant and in terms that are easily understandable by the authorizing person. The donation coordinator should be trained to appropriately answer the questions the authorizing person may have. Neither coercion nor inaccurate information shall be used in any manner to obtain authorization.*

### **D2.300 Signatures and Documentation**

#### **D2.310 Document of Gift**

In cases where a donor has executed a document of gift it may be acted upon (permits recovery) provided it meets applicable laws and regulations. Acceptable documentation may include a state driver's license, living will, advanced directive, state ID card, donor card, or photocopy thereof, and documentation that the donor registered in a donor registry.

#### **D2.320 Document of Authorization**

When a document of authorization is used it must contain the following signatures and related information:

- 1) the authorizing person's signature and:
  - a) name;
  - b) mailing address (NOTE: If requested by the authorizing person, only an email address may be documented as the address but, in such cases, the authorizing person should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective

[forwarding or receipt of information.\);](#)

- c) phone number; and
  - d) relationship to the *donor*;
- 2) the *donation coordinator's signature* and:
- a) the date; and
  - b) identity of their organization;
- 3) the *signature* of each *witness* if *witnessing* is required by law or regulation;
- 4) documentation that the Core Elements were used; and
- 5) a statement granting *authorization* for *tissue recovery*.

### **D2.330 Methods of Obtaining Authorization**

Legal *authorization* can be obtained using different methods. When *authorization* is obtained:

- 1) **in person**, the *authorizing person* must read and sign the document of *authorization*.
- 2) **by telephone**, the person obtaining the *authorization* shall read to the *authorizing person* the document of *authorization* or, alternatively, shall present each of the Core Elements described in ~~Standard~~ D2.400.

This telephone conversation *shall* be recorded. There *shall* be documentation that the *authorization* was obtained by telephone.

A sampling plan *must* be adopted that verifies that recordings match the content in the written *document of authorization*. This *verification* must be performed by someone other than the *donation coordinator* or *witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means is feasible for documenting *authorization*, the conversation *should* be *witnessed* by a third person. [Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale \(e.g., such as the FDA Guide to Inspection of Quality Systems\).](#)

- 3) **using a facsimile transmission**, a copy of the *document of authorization* is provided to the *authorizing person*. The *authorizing person* shall return the signed *document of authorization* by facsimile transmission. A *donation coordinator* shall be available to respond to questions posed by the *authorizing person*.

A sampling plan *must* be adopted that *verifies signatures* received by facsimile. This *verification* must be performed by someone other than the *donation coordinator* or *witness*. [Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale \(e.g., such as the FDA Guide to Inspection of Quality Systems\).](#)

- 4) **using an electronic transmission**, a copy of the *document of authorization* is provided to the *authorizing person*. The *authorizing person* shall electronically respond (e.g., by e-mail) that he/she has read the *document of authorization*, is authorized to grant *authorization*, and is granting such *authorization*. A *donation coordinator* shall be available to respond to questions posed by the *authorizing person*.

A *document of authorization* received by electronic transmission *should* be verified pursuant to the relevant law on electronic *signatures*, such as the Uniform Electronic Transactions Act of the relevant state. An electronically transmitted, read-only or otherwise protected *document of authorization* may be used.

#### **D2.400 Core Elements for Authorization**

The *document of authorization* shall contain *adequate information*. No *document of authorization* from an *authorizing person* shall be acted upon if it does not contain the following Core Elements. These Core Elements also apply to ~~Standard~~ D2.500.

Core Elements:

- 1) the name of the *Donor*;
- 2) the name, mailing address, and telephone number of the *authorizing person*, and his/her relationship to the *donor* (NOTE: If requested by the *authorizing person*, only an email address may be documented as the address but, in such cases, the *authorizing person* should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.);
- 3) an explanation that the *tissue* is a gift, and that neither the *donor's* estate nor the *authorizing person* will receive monetary compensation or valuable consideration for it;
- 4) a description of the general types of *tissue* to be *recovered*;
- 5) a description of the permitted use(s) of the *recovered tissues* (i.e., *transplant*, therapy, research, or education);
- 6) an explanation that *recovery* of *tissue* requires the following actions, and the *document of gift/authorization* thus specifically *authorizes*:
  - a) access to, and required disclosure of, the *Donor's* medical and other relevant *records*;
  - b) testing and reporting for transmissible diseases;
  - c) the removal of specimens which *may* include, but are not limited to, ~~the spleen, lymph nodes, and blood~~ or *tissue* samples for the purposes of *biopsy* or other testing necessary for determination of *donor* eligibility ~~determining suitability and/or compatibility of *donor* and recipient;~~
  - d) the release to the *tissue bank* of any and all *records* and reports of a Medical Examiner, Coroner or Pathologist (e.g., *autopsy report*); and
  - e) such other requirements as may be applicable for the specific donation or *tissue bank*, such as transport of the *donor's* body, archiving of samples, photographic or other imaging, etc.

- 7) contact information for the organization represented by the *donation coordinator*; and
- 8) any additional information required by laws or regulations.

The following information *should* be provided to an *authorizing person*:

- 1) a general description of the *recovery* e.g., timing, relocation of *donor* if applicable, contact information, etc.;
- 2) an explanation that costs directly related to the evaluation, *recovery*, *preservation*, and placement of the *tissues* will not be charged to the family;
- 3) an explanation regarding the impact the donation process may have on burial arrangements and on appearance of the *donor's* body; and
- 4) an explanation that the *document of authorization* is available.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that *tissue* may be ~~transplanted abroad~~ distributed internationally, *must* be included.

When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining *authorization* for a potential organ and *tissue* donation, the *tissue bank* for which the *authorization* is being obtained *shall* request that the OPO or other entity follow the *procedure* and utilize a *document of authorization* that satisfies the requirements of ~~Standard D2.000~~.

For a *donor* one month (28 days) of age or less, adequate consent pursuant to law *shall* be obtained for collection of blood from the birth mother ~~needed~~ that will be used for testing.

## **D2.500 Notification of Gift**

In cases where the gift is authorized by a *donor's* own *document of gift* (i.e., first person consent), including a *document of gift* recorded in a *donor registry* (i.e., *donor* designation), and where law mandates *notification*, such *notification shall* be made pursuant to law.

In all other cases, prior to transport of the *donor's* body or *recovery*, the *donation coordinator* ***should*** 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. The information to be provided in the *notification* ***should*** contain, at a minimum, Core Elements of *authorization* but at no time *shall* the *donation coordinator* indicate that the recipient of the information is empowered to revoke or amend the gift made by the *donor*.

The *donation coordinator* ***should*** inquire during the *notification* whether the notified person is aware of any revocation or refusal made by the *donor*.

*Notification*, if made, *shall* be documented.

Where good faith efforts to *notify* an appropriate person of the gift fail to result in actual *notification* within a time frame compatible with the successful *recovery* of the *tissue*, the attempt to notify *shall* be documented, and *recovery may* proceed.

## **D2.600 Services to Donor Families**

*Services to donor families or referral to a support system must be offered to the authorizing person. Subsequent communications and periodic evaluation of services shall be documented, maintained, and readily available. See AATB Guidance Document No. 4.*

## **D3.000 INFORMED CONSENT FOR LIVING DONORS AND CLIENT DEPOSITORS**

### **D3.100 Requirements**

*Informed consent to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a living donor or their legal representative, or from a client depositor in accordance with applicable laws or regulations. This informed consent shall be documented in a record of informed consent, the original or a copy of which shall be maintained in the ~~living donor's~~ or *client depositor's record* at the tissue bank responsible for recovery, collection or acquisition, as well as in the ~~living donor's record~~ at the tissue bank whose Medical Director is responsible for the donor suitability eligibility determination. In the case of an electronic or voice recorded record of informed consent, the original recording should be maintained in reproducible form.*

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of tissues for transplantation, therapy, research, or education.

### **D3.200 Conditions**

*Adequate information concerning the recovery, collection, or acquisition of tissue shall be presented in a language in which the living donor or their legal representative, or the client depositor is conversant, and in terms that are easily understandable by them ~~a living donor or client depositor~~. The donation coordinator should be trained to appropriately answer the questions the living donor, their legal representative, or the client depositor may have. Neither coercion nor inaccurate information shall be used in any manner to obtain informed consent.*

The potential donor or their legal representative shall not be under the influence of anesthesia or any drug that could influence his/her ability to give informed consent.

*Informed consent must be obtained prior to ~~the recovery~~ or acquisition, or when not possible and recovery or acquisition has already occurred, as soon as practical ~~after the recovery and~~ before use of the tissue.*

### **D3.300 Signatures and Documentation**

The record of informed consent must comply with applicable laws and regulations. It must contain, at a minimum,

- 1) the living donor's signature or their legal representative's signature, or the client depositor's signature and:
  - a) name;
  - b) mailing address (NOTE: If requested by the living donor, their legal representative, or the client depositor, only an email address may be documented as the address but, in such



cases, the *living donor*, their legal representative, or the *client depositor* should permit its use and *should* be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.);

- c) phone number;
- 2) the *donation coordinator's signature* and:
  - a) the date; and
  - b) identity of their organization;
- 3) the *signature* of each *witness* if *witnessing* is required by law or regulation;
- 4) documentation that the Core Elements for *informed consent* ([see D3.400](#)) were used;
- 5) a statement that the *living donor* or [their legal representative](#), or [the client depositor](#) understands what has been read or explained and is granting *informed consent* for *tissue recovery, collection, or acquisition*; and
- 6) a statement that the *living donor* or [their legal representative](#), or [the client depositor](#) has been informed that his/her name and address, as well as required *records*, shall be kept on file by the *tissue bank* or *reproductive tissue bank*.

### **D3.310 Methods of Obtaining Informed Consent**

*Informed consent* can be obtained using different methods, if and as authorized by law or regulation. The methods below appear in preferential order. When *informed consent* is obtained:

- 1) **in person**, the *living donor*, [their legal representative](#), or [the client depositor](#) must read and sign the [record of informed consent](#).
- 2) **by telephone**, the person obtaining the *informed consent* shall read to the *living donor*, [their legal representative](#), or [the client depositor](#) the [record of informed consent](#) or, alternatively, shall present each of the Core Elements described at [Standard D3.400](#).

This telephone conversation shall be recorded and it shall be documented that the *informed consent* was obtained by telephone. A sampling plan must be adopted that verifies that recordings match the content in the written [record of informed consent](#). This verification must be performed by someone other than the *donation coordinator* or *witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means are feasible for documenting *informed consent*, the *informed consent* may be made telephonically and should be witnessed by a third person. [Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale \(e.g., such as the FDA Guide to Inspection of Quality Systems\).](#)

- 3) **using a facsimile transmission**, a copy of the [record of informed consent](#) is provided to the *living donor*, [their legal representative](#), or [the client depositor](#). The *living donor*, [their legal representative](#), or [the client depositor](#) shall return

the signed record of informed consent by facsimile transmission. A *donation coordinator* shall be available to respond to questions posed by the *living donor*, their legal representative, or the client depositor.

A sampling plan *must* be adopted that *verifies signatures* received by facsimile. This *verification must* be performed by someone other than the *donation coordinator* or *witness*. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

- 4) **using an electronic transmission**, a copy of the record of informed consent is provided to the *living donor*, their legal representative, or the client depositor. The *living donor*, their legal representative, or the client depositor shall electronically respond (e.g., by e-mail) that he/she has read the record of informed consent, and is granting such *informed consent*. A *donation coordinator* shall be available to respond to questions posed ~~by the living donor or client depositor~~.

A record of informed consent received by electronic transmission *should* be verified pursuant to the relevant law on electronic *signatures*, such as the Uniform Electronic Transactions Act, of the relevant state. An electronically transmitted, read-only or otherwise protected record of informed consent may be used.

### **D3.400 Core Elements for Informed Consent**

No *informed consent* from a *living donor*, their legal representative, or a *client depositor* shall be acted upon if it does not contain the following Core Elements.

Core Elements:

- 1) the name of the *living donor* or *client depositor*; or
- 2) the identity of the person authorized by law to consent on behalf of the *living donor* or *client depositor* and his/her relationship to the subject including name, address, and telephone number;
- 3) if applicable, an explanation that the *tissue* is a gift, and that the *living donor* or their legal representative will not receive monetary compensation or valuable consideration for it;
- 4) a description of the general types of *tissue* to be *recovered*, *collected*, or acquired and any information pertinent to the specific *recovery*, *collection*, or acquisition contemplated;
- 5) a description of the permitted use(s) of the *tissues* (i.e., *transplant*, therapy, research, or education);
- 6) a description of the general purposes for which the *tissue* may be used;
- 7) a legally adequate release of the relevant medical records of the living donor's, their legal representative (when applicable), or of the client depositor's relevant medical records;
- 8) permission to test for disease, if applicable;

- 9) a statement that confirmed positive test results will be reported or disclosed if required by law or regulation (e.g., to the *living donor*, [their legal representative](#), or [the client depositor](#), to the attending physician, to appropriate health officials);
- 10) contact information for the organization represented by the *donation coordinator*;
- 11) information concerning possible risks and benefits to the *living donor*, [their legal representative](#), or [the client depositor](#), if applicable; and
- 12) any additional information required by laws or regulations.

[Any explanation required by law, such as an explanation that multiple organizations \(nonprofit and/or for profit\) may be involved in facilitating the gift\(s\) and/or reference to the possibility that \*tissue\* may be \*distributed\* internationally, must be included.](#)

- (R) In the case of a *client depositor* the [record of informed consent](#) shall also include details about costs of *tissue cryopreservation*, *storage*, *distribution* and *disposition* options.

In the case of an *anonymous donor*, the [record of informed consent](#) shall also include details about monetary compensation. See ~~Standard~~ D1.100.

### **D3.500 Services Involving Living Donors**

- (BT) [Services shall be developed that provide answers to questions posed by the birth mother after delivery.](#)

## **D4.000 DONOR SCREENING AND TESTING ~~SUITABILITY~~**

### **D4.100 ~~General~~ Donor Screening**

*Donor [eligibility](#) ~~suitability~~ criteria shall be established by the Medical Director and shall not conflict with these Standards. Each donor shall be evaluated according to established criteria. ~~The suitability of each donor shall be determined by the Medical Director or licensed physician designee upon review of all records as specified in F1.100 and in accordance with the SOPM.~~*

- (A) *Donor [eligibility](#) ~~suitability~~ criteria shall be established and documented by a licensed physician caring for the patient donor [autologous donor](#). It is not necessary to document a *physical examination*, a *donor risk assessment interview*, or medical history and medical record review for *autologous tissue* in the *tissue bank records*.*
- (LD) *Criteria for accepting *living donors* shall be established by the Medical Director or licensed physician designee.*
- (BT) [Except for \*autologous\* donations, the health status of the infant\(s\) shall be assessed in regard to information that could affect the \*quality\* or \*safety\* of the \*tissue\* for \*transplantation\*. Protocols shall be established for reviewing information at the time of the infant's delivery. Policies and procedures should be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written procedures must describe how information is evaluated.](#)
- (S) *Potential donors shall be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and *skin* condition.*

- (C) Heart donors shall also ~~meet the following criteria:~~
- ~~1) Recovery of a heart from an anencephalic infant shall begin only after Asystole;~~
  - ~~2) In the case of suspected Sudden Infant Death Syndrome (SIDS), an autopsy should be performed and results reviewed to confirm the cause of death; and~~
  - ~~3) Heart valve donors shall be evaluated for the risk of Chagas' disease.~~
- (R) Criteria for accepting *client depositors* and potential *reproductive cell and tissue donors* shall be established by the Medical Director or licensed physician designee.

#### ~~D4.400~~ **D4.110 Age Criteria**

The Medical Director and/or *tissue bank* Medical Advisory Committee shall determine donor age criteria ~~for donor suitability.~~

- (A) There are no age limits for *autologous tissue* donation.
- (BT) There is no age limit for the birth mother, however, policies and procedures shall be written regarding gestational age limits.
- (R) *Semen donors* shall be younger than 40 years of age to minimize the risk of genetic anomalies except with the written agreement of the user physician. ~~For Donated embryos, the female (oocyte) Oocyte donors~~ shall be younger than 35 years, unless an exception has been made by the Medical Director with documented agreement of the user physician.

#### ~~D4.200~~ **Assessment**

##### **D4.120 Physical Assessment**

Prior to the *recovery* of *tissue* from a ~~potential~~ deceased *donor*, a *physical assessment* shall be performed by a *responsible person*. This shall be a recent ante-mortem or postmortem *physical assessment* to identify evidence of: high risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, signs of trauma or infection to the potential recovery sites body where recovery of tissue is planned. If any of the following signs are observed or noted in any other available *record*, and are deemed to be an indication of these risks, then the *tissue* shall be rejected:

Note: Each risk type is followed by observational wording in parentheses suggestive of terminology that correlates with each listing. See Appendix III. AATB's Guidance Document No. 1, Tissue Donor Physical Assessment Form).

- 1) physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, chancroid (genital lesions);
- 2) physical evidence for risk of, or evidence of, syphilis (genital lesions, rash, skin lesion [non-genital]);
- 3) for a male donor, physical evidence consistent with anal intercourse including

perianal condyloma (insertion trauma, perianal lesions);

- 4) **p**hysical evidence of non-medical percutaneous drug use such as needle tracks (and/or non-medical injection sites), including examination of tattoos (which may be covering needle tracks);
- 5) **d**isseminated lymphadenopathy (enlarged lymph nodes);
- 6) **u**nexplained oral thrush (white spots in the mouth);
- 7) **b**lue or purple spots consistent with Kaposi's sarcoma (blue/purple [gray/black] spots/lesions);
- 8) **p**hysical evidence of recent tattooing, ear piercing, or body piercing (tattoos/piercings should be described);
- 9) **u**nexplained jaundice, hepatomegaly, or icterus. Note: Hepatomegaly may not be apparent in a *physical assessment* unless an autopsy is performed (enlarged liver, jaundice, icterus);
- 10) **p**hysical evidence of sepsis, such as unexplained generalized rash/generalized petechiae, or fever (rash);
- 11) **l**arge scab consistent with recent smallpox immunization (scab);
- 12) **e**czema vaccinatum (lesion, scab);
- 13) **g**eneralized vesicular rash, generalized vaccinia (rash);
- 14) **s**everely necrotic lesion consistent with vaccinia necrosum (lesion); and/or
- 15) **c**orneal scarring consistent with vaccinal keratitis (abnormal ocular finding, scarring).

~~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 No. 1. This method, or an equivalent method, shall be implemented.~~

The form and instructions in Appendix III *must* be used to document the *tissue donor physical assessment*.

- (S) The *physical assessment* shall include documentation of findings and conditions that may affect the *quality* or quantity of *skin recovered*.

#### **D4.130 Physical Examination**

- (LD) Except for *autologous* and *embryo* donations, prior to the donation of *tissue* from a potential *living donor*, a *physical examination* shall be performed by the Medical Director or **licensed** physician designee, or by a physician involved with the individual's medical care, or designee as permitted by law. If an examination of a *living donor* was performed for other reasons, review of the findings of such an examination *shall* be performed and documented in the *donor's record*, as well as all other examination findings. After a

*donor risk assessment interview* is completed, if any history is suspect, a directed *physical examination* shall be performed. The directed examination shall include any of the above applicable items (see D4.120) that would assist with information to determine whether there is evidence of high risk behavior. ~~The physical examination should be used to determine overall general health of the donor.~~

(BT) In addition to the (LD) standard above, a *physical examination* of the birth mother *must* be performed during admission for delivery or within 14 days prior to delivery.

(R) A *physical examination* must be performed on all *anonymous* and *directed semen* and *oocyte donors*. A repeat *physical examination* shall be performed on *anonymous semen donors* at least every 6 months (180 days) while the donor is actively collecting samples in the program.

*Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the semen.*

#### **~~D4.220~~ D4.140 Donor Risk Assessment Interview (DRAI)**

A *documented dialogue* ~~An inquiry~~ shall be conducted with the *donor* (if living) or the deceased *donor's* next of kin, the nearest available relative, a member of the *donor's* household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician, using a standardized questionnaire. Questions shall be formulated using these *Standards*, current federal regulations and guidance.

Questions shall be included that evaluate past medical history for conditions that could constitute a contraindication to the release of *tissue* for *transplantation* (e.g., certain infectious diseases, malignancies, and degenerative neurologic disorders), as defined in these *Standards* (see Appendix II).

For all donors one month (28 days) of age or less, the infant and the birth mother shall be screened for risk of *relevant communicable disease agents and diseases* (RCDADs) and the birth mother's blood *must* be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.

~~The inquiry record~~ *donor risk assessment interview* shall document the *donor's* name, and the relationship between the *donor* and the interviewee(s) and shall indicate the name(s) of the interviewer(s) and interviewee(s). The questionnaire shall be maintained as part of the *donor's record*.

(A) The *tissue bank* shall have a policy for obtaining information from the patient's physician as to whether the *autologous donor* is at high risk for viral hepatitis or HIV infection.

(R) The donor's risk assessment shall include a review of personal alcohol and drug use and sexually transmissible diseases in the *donor* and partner(s). The screening process also shall include any history of chemical and/or radiation exposure as well as family medical history and genetic background. An abbreviated *donor* screening must be obtained at each repeat donation and reviewed by a *responsible person*. The abbreviated screening must determine and document any changes in the *donor's*

medical, social, travel, and sexual behavior history (including risk factors) since the previous donation that would make the *donor* ineligible.

(BT) The *donor risk assessment interview* of the birth mother *shall* be obtained, or previous *donor risk assessment interview* information *verified*, no more than 14 days prior to delivery. If this interview is performed after delivery it *must* be completed within 14 days of delivery.

(LD) Interviews *must* be administered by trained staff, or if self-administered, a trained staff member *must* review and *verify* answers with the *donor* in order to facilitate comprehension and provision of accurate answers.

#### ~~D4.221~~ **D4.141 (R) Family History and Genetic Background**

(BT) If genetic testing has been performed or a genetic history has been obtained and the information is available, it *should* be considered for the determination of *donor* eligibility.

(R) A minimum of a three-generation family history *shall* be elicited from each prospective *donor*. If a biological family member in the prospective *donor's* family is adopted, Medical Director discretion *must* be made to determine if sufficient family history is provided to determine *donor* eligibility. The genetic history *should* be evaluated by an individual with appropriate clinical genetics education and/or training. Any significant condition in a prospective *donor* or *donor's* family history that would pose a risk of producing an offspring with a serious genetic disease or defect greater than the risk in the general population *shall* disqualify him/her as a *donor*, with the following exceptions:

- 1) *Anonymous donors* whose family history indicates that he/she is at risk for carrying a genetic defect *may* be accepted only if a test to detect carrier status is performed and is negative for the mutation that is known to occur in the family; or
- 2) ~~Family members selected as *directed donors* by the prospective *donor* and *recipient*.~~ *Directed gamete donors* and *anonymous or directed embryo donors* with any family history indicating he/she is at risk for carrying a genetic defect/condition *may* be accepted, provided the genetic risk to offspring is evaluated in writing and the *recipient(s)* (R) has reviewed the evaluation, been offered additional genetic testing, and completed an informed consent.

If indicated by medical history, family history, or ethnic background, *anonymous donors* *should* be screened for Tay-Sachs disease, thalassemia, sickle cell trait, spinal muscular atrophy, and/or cystic fibrosis.

#### ~~D4.230~~ **D4.150 Relevant Medical Records Review**

Prior to *tissue* donation, a preliminary review of readily available *relevant medical records* *shall* be conducted by a trained individual.



This review *shall* include but *may* not be limited to:

- 1) evidence of significant active infection at the time of donation for *relevant communicable disease agents or diseases* (RCDADs) including signs and/or symptoms of viral and fungal infection, bacteremia or sepsis;
  - 2) risk factors for *relevant communicable disease agents or diseases* (RCDADs) as specified in Appendix II; and
  - 3) additional *tissue donor* specific criteria as documented in the *SOPM* and compliant with written agreements/contracts.
- (A) Except for *skin, autologous* donation *should* not be undertaken when the *autologous donor* has, or is being treated for, bacteremia or other significant bacterial infection that can be associated with bacteremia, unless such *tissue* will be secondarily *sterilized* prior to *transplantation* or treated in such a manner to minimize microbial contamination.

~~Prior to release of tissue for transplantation, the Medical Director or licensed physician designee shall determine donor suitability. If the donor's death did not occur in a hospital, or when no *Third Party Records* are available that can be used to establish a likely cause of death, and if no autopsy was performed, a *Certified Copy* of the death certificate must be included in the donor record. The Medical Director or licensed physician designee shall determine donor suitability based on a review and evaluation of the donor's *Relevant Medical Records* or a summary of these generated by a trained individual. The determination of suitability shall be based on the *SOPM*, these *Standards* and applicable laws and regulations.~~

#### **~~D4.240 Donor Autopsy Report~~**

~~If an autopsy was performed, the tissue bank's Medical Director or licensed physician designee shall review the autopsy report or a summary of findings prior to the release of tissue to inventory. If a copy of the autopsy report is not available for the donor's record, the cause of death and other pertinent autopsy findings shall be documented in the donor's record. If it is determined that an autopsy was not performed due to infectious disease risk or, if an autopsy was performed, if any special precautions were taken that would suggest risk of a communicable disease in the donor, this information should be considered.~~

#### **~~D4.300 Disease Screening~~**

- (A) ~~The *tissue bank* shall have a policy for obtaining information from the patient's physician as to whether the patient/donor is at high risk for hepatitis or HIV infection.~~

#### **~~D4.310 Infections~~**

~~The Medical Director or licensed physician designee *shall* not release *allogeneic* tissue for *transplantation* from donors who exhibit any of the following findings:~~

- ~~1) Evidence, detected by review of *relevant medical records*, of significant active infection at the time of donation for Relevant Communicable Disease Agents or Diseases (RCDADs). These include, but are not limited to: septicemia, viral disease (e.g., HIV, viral hepatitis, WNV, rabies, etc.), human transmissible~~

~~spongiform encephalopathies, untreated syphilis, clinically active tuberculosis, leprosy (Hansen's disease), or systemic mycosis; and/or~~

~~2) Risk factors for Relevant Communicable Disease Agents and Diseases (RCDADs) as specified in Appendix II.~~

~~(A) Except for skin, autologous donation *should* not be undertaken when the donor patient has, or is being treated for, bacteremia or other significant bacterial infection that can be associated with bacteremia, unless such tissue will be secondarily *Sterilized* prior to transplantation or treated in such a manner to minimize microbial contamination.~~

~~(R) *Semen Donors* shall not exhibit an infectious skin disease that creates a risk of contamination of the *Semen*. For all reproductive donors, there shall not be evidence of infection within the past twelve months with *Chlamydia trachomatis* and/or *Neisseria gonorrhea* unless the reproductive tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract.~~

~~(DM) After the *Dura Mater* has been recovered, a qualified pathologist shall perform an examination of the donor's brain. Following fresh examination, the brain should be fixed and sliced, gross examination of the entire brain should be conducted (including multiple cross sections), and multiple specimens of tissue should be obtained (from different parts of the brain, e.g., frontal and occipital lobes) for histological examination. The gross and histologic findings must be assessed for any evidence suggestive of transmissible spongiform encephalopathy (TSE).~~

#### **~~D4.320 Miscellaneous Adverse Conditions~~**

~~Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*:~~

~~1) History of autoimmune diseases; or~~

~~2) Ingestion of, or exposure to, toxic substances.~~

~~(MS) In addition to the general exclusion criteria, the following medical conditions shall also preclude musculoskeletal tissue donation:~~

~~1) Rheumatoid arthritis;~~

~~2) Systemic lupus erythematosus;~~

~~3) Polyarteritis nodosa;~~

~~4) Sarcoidosis; and~~

~~5) Clinically significant metabolic bone disease.~~

~~(C) Heart donors shall also meet the following criteria:~~

~~1) There shall be no history of bacterial endocarditis, rheumatic fever, or~~

a cardiomyopathy of viral or idiopathic etiology;

2) Any history of previous cardiac surgery (i.e., CABG), semilunar valvular disease, closed chest massage (CPR), cardiac defibrillations, penetrating cardiac injury, or other potentially deleterious cardiac intervention shall be evaluated on a case-by-case basis; and

3) Mitral valve donors shall not have a history of mitral valve disease, including mitral valve prolapse.

(V) ~~Vascular donors shall also meet the following criteria:~~

1) ~~Veins—There shall be no history of vein stripping, varicose veins, or evidence of venous insufficiency;~~

2) ~~Arteries—There shall be no known (reported) history of peripheral vascular disease or systemic vasculitis; and~~

3) ~~Trauma shall be evaluated on a case-by-case basis for any vascular tissue Recovery.~~

#### **D4.330 Risk Factors**

~~Tissue shall not be distributed from donors, including maternal donors of *Fetal Tissue* or neonatal tissue, who have engaged in behaviors defined as high risk for transmission of Relevant Communicable Disease Agents or Diseases (RCDADs). See Appendix II. This information shall be obtained via a *Donor Risk Assessment Interview*, *Physical Assessment/Physical Examination*, and by review of other available *Relevant Medical Records*.~~

#### **D4.340 Malignancies**

~~Donors with current or prior diagnosis of malignancy shall be evaluated by the Medical Director or licensed physician designee for suitability in accordance with the tissue bank's *SOPM*. The evaluation shall include: the type of malignancy, clinical course, and treatment prior to acceptance of a donor. The evaluation and reasons for acceptance shall be documented in the donor's record.~~

#### **D4.350 D4.200 Blood Tests Donor Testing**

##### **~~D4.351~~ D4.210 Blood Specimens**

Except as otherwise specified in ~~tissue-specific standards~~ for certain reproductive tissue donors, infectious disease testing of donor blood specimens *shall* be performed for each *tissue donor* ~~(including maternal donors of *Fetal Tissue* or neonatal tissue)~~, on a specimen collected at the time of donation or within ~~seven~~ 7 days prior to or after donation. If the *donor* is one month (28 days) of age or less, a blood specimen from the birth mother *must* be collected within ~~seven~~ 7 days prior to or after *tissue* donation and tested instead of a specimen from the infant donor. There *shall* be written *procedures* for all significant steps in the infectious disease testing process, including blood specimen collection (i.e., documentation of date/time of collection, a donor identifier), documentation of the *verification* of specimen *labeling*, and use of appropriate blood specimen types, *labels*, and instructions for specimen handling. *Procedures shall* conform to the test kit manufacturer's instructions for use contained in the package inserts. Specimen collection, storage, and handling *procedures shall* be

described in the *SOPM*.

- (R) For [anonymous and directed](#) oocyte donors, the ~~donor~~ blood specimen *must* be collected within 30 days prior to oocyte retrieval [collection](#), or within 7 days post donation. ~~For repeat Semen Donor requirements, see D4.360 Repeat Testing of Living Donors (R).~~ [Samples for infectious disease testing of anonymous and directed semen donors must be obtained within 7 days of initial semen collection. See D4.360 for testing requirements for embryo donors.](#)

#### ~~D4.352~~ [D4.211](#) Plasma Dilution

*Tissue* from a *donor* who is older than 12 years of age *shall* be determined to be not suitable for *transplantation* if blood loss is known or suspected to have occurred and there has been transfusion/infusion of more than 2,000 milliliters (mL) of blood (e.g., whole blood, or red blood cells) or *colloids* within 48 hours; or more than 2,000 mL of *crystalloids* within one hour; or any combination thereof, prior to *asystole* or the collection of a blood specimen, whichever occurred earlier, unless:

- 1) a pre-transfusion or pre-infusion blood specimen from the *tissue donor* is available for infectious disease testing; or
- 2) an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the *tissue donor* to ensure that there has not been *plasma dilution* sufficient to affect test results.

*Tissue* from a *donor* who is 12 years of age or less who has been transfused or infused at all, *shall* be determined to be not suitable for *transplantation* unless a pre-transfusion or pre-infusion blood specimen from the *tissue donor* is available for infectious disease testing, or an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the *tissue donor* to ensure that there has not been *plasma dilution* sufficient to affect test results.

When the fluids transfused are in the “blood” category (alone, or in combination with *colloids* and/or *crystalloids*), a comparison of the total volume of these fluids with the *donor’s* estimated blood volume *shall* be performed, in addition to a comparison of the total volume of *colloids* and/or *crystalloids* with the *donor’s* estimated plasma volume. Since every possible clinical situation cannot be described where *plasma dilution may* affect test results, the *SOPM should* describe how to address additional circumstances when *plasma dilution may* have occurred (e.g., large volumes of transfusions/ infusions administered in the absence of blood loss). It may be necessary to use a pre-transfusion/infusion blood specimen or apply an algorithm in those instances.

Alternative algorithms to evaluate *plasma dilution* can be used if justified.

#### ~~D4.353~~ [D4.220](#) Infectious Disease Testing

Results of initial infectious disease and/or confirmatory testing *shall* be used as one component of determining *donor suitability* [eligibility](#). Testing used for *donor suitability* [eligibility](#) *shall* be performed by laboratories that are registered with FDA

as a tissue establishment for testing and are either certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, and test kit licensing/approval.

FDA-licensed, approved, or cleared **donor screening** tests *must* be used, except when testing for *Chlamydia* or *gonorrhea* in which case, an FDA-licensed, cleared or approved diagnostic test *must* be used.

- ~~1) for syphilis testing, treponemal-specific or non-treponemal donor screening tests-  
OR diagnostic tests may be used, but both types must be FDA-licensed, cleared, or approved; and~~
- ~~2) when testing for chlamydia or gonorrhea, an FDA-licensed, cleared or approved diagnostic test must be used.~~

A new test *shall* be implemented when AATB and/or FDA issues notification to that effect. Prior to that time, use of the new test, even if FDA-licensed, approved, or cleared for *donor* screening ~~specimens~~, is voluntary. Tests specifically labeled for ~~cadaveric specimens~~ use with specimens collected after the donor's heart has stopped beating instead of a more generally labeled test *shall* be used when applicable and when available.\*

A list of *donor* screening tests that have been licensed for use with specimens collected after the *donor's* heart has stopped beating can be accessed at the FDA/CBER website.

\*See AATB Bulletin No. 06-45 "Intent of Update to Standard D4.353." (Note: this standard is currently D4.220)

Rapid antigen and/or antibody testing for infectious disease *may* be performed in addition to the required tests. Results of these tests *must* be evaluated (see F1.140) and shared (see D4.300) in accordance with policies and *procedures*.

If a laboratory that performs organ *donor* testing performs the initial testing in duplicate or triplicate, the *tissue bank* *must* obtain and review the results of all individual tests performed. Individual test results *shall* be shared in accordance with B1.510 ~~Written Agreements/Contracts, D4.500~~ D4.300 Information Sharing, and K1.100 ~~Basic Elements of a Quality Assurance Program~~.

All *tissue* from *donors* who test repeatedly reactive on a required screening test *shall* be *quarantined* and *shall* not be used for *transplantation*. There *shall* be written *procedures* for all significant steps in the infectious disease testing process that *shall* conform to the manufacturer's instructions for use contained in the package inserts for required tests. These *procedures* *shall* be readily available to the personnel in the areas where the *procedures* are performed unless impractical. The manufacturer's instructions *shall* be followed in regard to acceptable *donor* specimens and their handling. *Donor* sample testing *shall* be performed and test results interpreted according to the manufacturer's instructions in the package insert for the particular

infectious disease marker.

Additional testing to confirm or supplement infectious disease test results *may* be performed at the discretion of the Medical Director using FDA-licensed, confirmatory test kits when commercially available. Results of infectious disease testing *shall* be evaluated prior to disclosure [of availability](#) of positive test results (see ~~Standard-~~ D4.232).

#### ~~D4.354~~ **[D4.230](#) Required Infectious Disease Tests**

Excluding *autologous, [embryo donor, and client depositor](#) tissue, oocytes and embryos*, all human *tissue* intended for *transplantation* shall be from *donors* who are tested and found to be negative for:

- 1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti- HIV-1 and anti-HIV-2);
- 2) nucleic acid test (NAT) for HIV-1;
- 3) hepatitis B surface antigen (HBsAg);
- [4\) nucleic acid test \(NAT\) for the hepatitis B virus \(HBV\);](#)
- [45\) total antibodies to hepatitis B core antigen \(anti-HBc—total, meaning IgG and IgM\);](#)
- [56\) antibodies to the hepatitis C virus \(anti-HCV\);](#)
- [67\) nucleic acid test \(NAT\) for HCV; and](#)
- [78\) syphilis \(a non-treponemal or treponemal-specific assay \*may\* be performed\).](#)

*Donors* of viable leukocyte-rich *tissue* (e.g., *semen*, certain (CT)) *shall* also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of *donors* of other *tissue* types *may* be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

All test results *shall* be documented in the *donor's record*.

- (R) In addition to the infectious disease tests listed above, all *anonymous* and *directed semen* and *oocyte donors* shall undergo testing for *Neisseria gonorrhea* and *Chlamydia trachomatis*. The manufacturer's requirements for specimens *must* be met. If the reproductive *tissue* is ~~procured~~ [collected](#) by a method that ensures freedom from contamination of the *tissue* by infectious disease organisms that may be present in the genitourinary tract, then these tests are not required.

All *anonymous* and *directed semen donors* shall also be tested for total antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).

~~All anonymous and directed Oocyte Donors shall be tested for all above-listed tests, excluding antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II) and total antibody to~~

cytomegalovirus (anti-CMV).

Required tests for *anonymous* and *directed embryo donors* are listed in D4.231.

*Client depositors* who deposit *semen*, testicular fluid or *tissues*, *oocytes* or ovarian *tissue*, or *embryos*, shall be tested prior to use for:

- 1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
- 2) hepatitis B surface antigen (HBsAg); and
- 3) antibodies to hepatitis C virus (anti-HCV).

~~All Oocyte Donors must undergo required testing within 30 days prior to egg retrieval, or within 7 days post donation. Samples for infectious disease testing of anonymous and directed Semen Donors must be obtained within 7 days of initial Semen Collection.~~

#### **D4.355 Interpretation of Infectious Disease Test Results**

~~Disposition of allogeneic tissue shall be based upon the interpretation of all infectious disease test results and shall be as follows:~~

- ~~1) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive on an FDA-licensed, approved, or cleared donor screening test for anti-HIV-1, anti-HIV-2, HBsAg, anti-HBe, or anti-HCV. When a birth mother's specimen is used for testing, these same rules apply.~~
- ~~2) Viable leukocyte rich tissue (e.g., semen) shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive (RR) on an FDA-licensed, approved, or cleared donor screening test for anti-HTLV-I or anti-HTLV-II.~~

~~The suitability of other human tissue for transplantation from donors whose specimens test RR for anti-HTLV-I or anti-HTLV-II shall be determined by the Medical Director.~~

~~Note: Law and/or regulation, including, where applicable, foreign laws and/or regulations, may differ in regard to a RR HTLV antibody test result and how this impacts the suitability of the donor's tissues for transplantation.~~

- ~~3) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen had a final test result of positive, repeat reactive, or repeatedly reactive on a screening test using a NAT assay. When a birth mother's specimen is used for testing, these same rules apply.~~
- ~~4) If a laboratory that performs organ donor testing performs the initial testing in duplicate or triplicate, the Tissue Bank must obtain and review the results of all individual tests performed. If any one of those initial tests~~



is reactive or positive, the tissue shall be determined not suitable for transplantation.

- 5) Tissue from a donor reactive for syphilis using an FDA-licensed, cleared, or approved **non**-treponemal screening assay may be used for transplantation only if the sample is found to be negative using an FDA-licensed, cleared or approved treponemal-specific confirmatory assay. If initial testing was performed using an FDA-licensed, cleared, or approved treponemal-specific confirmatory assay and was reactive, the tissue shall not be used for transplantation.
- 6) If results of additional infectious disease testing are received for tests that are not required, such test results must be included in the donor's medical record and any results from those tests must be considered when determining donor suitability. Procedure(s) shall be established for the interpretation of additional infectious disease test results.

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority regarding test kit licensing/approval apply.

- (A) — Determination of the final *disposition* of *tissue* in which a *donor's* blood sample tests positive is the responsibility of the donor-patient's licensed physician. If *tissue* from a *donor* who tests positive is to be stored in a *tissue bank*, refer to E4.400 Segregation of Tissue.
- (R) — Determination of the use of *Client Depositor* and/or *Directed Donor* reproductive tissues in cases where required test results are positive or repeatedly reactive must be documented according to protocols described at F2.200 Special Circumstances in Release of Reproductive Tissues (see note for CMV below).

Tissue from an anonymous *Semen Donor* who tests reactive for an active, acute infection with cytomegalovirus (CMV) shall not be deemed suitable for use. Tissue from an anonymous *Semen Donor* determined to be in a latent CMV status may be acceptable. Each individual bank shall develop a procedure for determining suitability for both anonymous and *Directed Donors*. Procedures must also include provisions for communicating CMV status to the end-user physician such that a decision can be made regarding use of a CMV positive (total IgG plus IgM) donor.

Tissue from a donor testing positive for chlamydia or gonorrhea shall not be suitable for use.

#### **D4.360 [D4.231](#) Repeat Testing of Living Donors**

- (R) All donated *semen* from both ~~directed and~~ *anonymous donors* shall be frozen and *quarantined* for at least 6 months (~~180 days~~). After such time and prior to release of *semen*, the *donor* shall be retested for anti-HIV-1, [HIV-1 NAT](#), anti-HIV-2, HBsAg, anti-HBc, [HBV NAT](#), anti-HCV, [HCV NAT](#), anti-HTLV-I, anti-HTLV-II, [syphilis](#), and for anti-CMV. *Anonymous donor semen* shall not be made available for use unless results of all tests, excluding CMV and syphilis, are

negative or nonreactive. Results of all testing performed *must* be interpreted as in [F1.140](#). All tests for infectious diseases *shall* be repeated at least every 6 months while the *semen donor* remains an active participant in the *donor* program and after any lapse exceeding 6 months.

*Oocyte donor tissue* is not subject to *quarantine* and the *donor* is not subject to repeat testing.

For *directed* or *anonymous donation* of *embryos* created by sexually intimate *client depositors*, the *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After the 6-month *quarantine* and prior to release of the *embryo(s)* for *transfer*, [appropriate measures should be taken to test](#) the sexually intimate *client depositor* male and female ~~shall be tested~~ for anti-HIV-1 anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, [HBV NAT](#), HCV NAT, and syphilis. In addition, the male ~~shall~~ [should](#) be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II.

For *directed* or *anonymous donation* of *embryos* created using one *anonymous* or *directed* egg or *sperm donor*, *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After such time and prior to release of the *embryo(s)* for *transfer*, [appropriate measures should be taken to test](#) the *client depositor* ~~shall be tested~~ for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, [HBV NAT](#), HCV NAT, and syphilis. If the *client depositor* is male, he ~~shall~~ [should](#) also be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II. A *Summary of Records for the gamete donor* [must](#) be provided prior to release. ~~If the embryos were acquired from a non-accredited facility and a directed sperm donor was used without a 6 month Quarantine and re-test, the directed sperm donor must also be re-tested for anti HIV 1, anti HIV 2, HBsAg, anti HBe, anti HCV, HIV 1 NAT, HCV NAT, and syphilis in addition to anti CMV, anti HTLV I, and HTLV II.~~

For *directed* or *anonymous donation* of *embryos* created using both an *anonymous* or *directed* egg and *sperm donor*, a *donor summary of records must* be obtained for both donors. ~~If the embryos were acquired from a non-accredited facility and a directed sperm donor was used without a 6 month Quarantine and re-test, the directed sperm donor must be re-tested following a 6 month Quarantine for anti HIV 1, anti HIV 2, HBsAg, anti HBe, anti HCV, HIV 1 NAT, HCV NAT, and syphilis in addition to anti CMV, anti HTLV I and anti HTLV II.~~

[“Appropriate measures” means using available resources to accomplish the testing. If the client depositor cannot be tested due to death or inability to locate the person, directed or anonymous donation of the embryos can still be completed.](#)

#### **~~D4.356~~ [D4.232](#) Disclosure and Availability of Positive Infectious Disease Test Results**

The *donor*, if living, *shall* be provided test results as required by applicable

law or regulation. For deceased *donors*, the *authorizing person* *should* be contacted regarding the availability of infectious disease test results that may be of medical significance as determined by the Medical Director or licensed physician designee. Contact *should* include the means by which available test results *should* be requested. If a *document of gift* was used (i.e., there is no *authorizing person*), contact regarding the availability of infectious disease test results *should* be made to the person who would have been the *authorizing person* had no gift been made during the life of the *donor*, or to the person authorized to make arrangements for final disposition of the body. These *records* *should* be provided upon written request as permitted by law or regulation. Positive test results *shall* be reported to state and/or local health department(s) as required by law or regulation.

Contact regarding availability and/or disclosure of test results *shall* be documented.

#### ~~D4.357~~ **D4.240 Archived Samples**

A serum or plasma sample from each *donor* *shall* be archived if any sample remains after testing. A policy *shall* be established to collect and archive serum, plasma, or hematopoietic *tissue* samples from *donors*. Samples *shall* be retained for ten years after the *recovery*, *collection*, [\*or acquisition\*](#) date. If a *donor* is determined to be unsuitable, archived serum, plasma, or hematopoietic *tissue* samples *should* still be retained for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

- (DM) Appropriate brain *tissue* specimens (i.e., formalin-fixed brain *tissue*, histological sections from examination of brain, *donor* serum) from each *donor* of *dura mater* *shall* be archived under appropriate storage conditions, and for the appropriate duration.
- (R) Archived serum or plasma from *reproductive donors* whose *tissue* has been *stored* but subsequently destroyed and never *distributed* does not require retention.

#### ~~D4.370~~ **D4.250 Semen Analysis**

- (R) **Semen Donors:** Prior to enrollment of a *donor* in the sperm *donor* program, his *semen* *shall* be tested for sperm quality and found acceptable for such parameters as sperm motility, concentration, and post-thaw motility. *Donors* *shall* be excluded unless the specimen meets criteria set by the Medical Director and, when appropriate, the Medical Advisory Committee. Criteria for *directed donors* *may* differ from those for *anonymous donors*. Sperm quality tests *shall* be repeated at a frequency determined by the *tissue bank*.

**Client Depositors:** A *semen* analysis, that includes sperm concentration and motility, at a minimum, *shall* be performed. The ~~Semen~~ *reproductive tissue bank* *shall* make pertinent test results available to the *client depositor's* physician.

#### ~~D4.500~~ **D4.300 Information Sharing**

The *tissue bank* that recovers *tissues* *must* have a *procedure(s)* for receiving, investigating, evaluating, and documenting *donor* information as well as how they will share *records* with

all establishments who are known to have also *recovered tissues*, or to have received *recovered tissues*, from the same *donor*:

- 1) *record sharing should occur as new information is received and this must be documented and included in the records*;
- 2) *relevant records that could affect suitability eligibility determinations must be sent without delay to tissue banks that will determine donor suitability eligibility of recovered tissues and/or the donor*;
- 3) *the tissue bank that recovers tissue must share tissue recovery culture (pre-sterilization/pre-disinfection culture) information with all tissue banks to which tissue from shared donors was sent. If defined in a written agreement, an eye bank can choose not to receive pre-sterilization/pre-disinfection culture results; and*
- 4) *if any tissue bank determines a donor to be unsuitable ineligible, this determination must be communicated in writing to the tissue bank that recovered tissues, and the tissue bank that recovered tissues must share this information with all establishments that are known to have recovered tissues, or to have received recovered tissues, from the same donor.*

Written *procedures must* describe how this information is received, evaluated, and disseminated in a timely fashion.

Any *tissue testing performed after it has been decontaminated/ disinfected or subjected to processing (e.g., in-process testing, post-processing microbiological testing, final cultures, graft suitability tests)* is not considered relevant *donor records* for the *tissue bank that recovered tissues* and, if such results are reported, would not be expected to be shared with *tissue banks who received recovered tissues from a shared donor*.

## **D5.000 RECOVERY, ~~AND COLLECTION, AND ACQUISITION~~ POLICIES AND PROCEDURES**

Policies and *procedures shall* be established for the *recovery, collection, or acquisition* of *tissue* in accordance with *Standards*. Reagents, supplies, materials, and equipment *shall* be of appropriate grade for intended use, and approval for use *shall* be documented. All *tissue must* be uniquely identified and traceable to the *donor from recovery, collection, or acquisition* through transport and receipt at the *processing or storage facility*. The environment in which *tissue* can be obtained, and techniques that *should* be used, *shall* be specified. *Recovery, collection, acquisition and preservation shall* occur within a time interval appropriate for retention of ~~biological functions~~ *tissue quality* and *shall* be compatible with intended use of the *tissue*. Detailed *records of the tissue donation shall* be maintained that include information regarding relevant packaging, transportation, and, *when applicable, donor reconstruction steps*.

### **D5.100 Reagents, Supplies, Materials, and Equipment**

All *critical supplies, reagents, materials, and equipment approved for use for recovery, collection, or acquisition shall* be identified and specifications (e.g., *sterile where applicable*) documented. A *record shall* be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, *lot* number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection *shall* be documented, including identification of the staff performing the inspection. The *tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used. All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers' instructions, unless qualified/validated for intended use or storage.*

All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with *tissue* shall be properly cleaned, ~~disinfected~~ decontaminated, and sterilized prior to use for *recovery*, *collection*, or acquisition according to written *procedures* prepared to prevent contamination or *cross-contamination*. *Records* shall be maintained that document sterilization steps. All reagents, supplies, and materials shall be used and stored in accordance with manufacturers' instructions unless qualified/validated for intended use or storage.

#### **D5.110 Stock Rotation**

Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items *should* be used first and not used if expired or quality has been compromised.

#### **D5.200 Donor Identification**

Each *donor* shall be assigned a unique *donor* identifier to facilitate *tracing* of the *tissue* from the *donor* and to final *disposition* of each *tissue*.

#### **D5.210 Verification Procedures**

##### **D5.211 Confirmation**

Prior to *recovery* or *collection*, staff shall confirm that in the case of a deceased *donor*, *authorization* for donation has been obtained and documented in a *document of gift/authorization*. ~~and~~ In the case of a *living donor*, *informed consent* ~~has been~~ must be obtained and documented prior to the initial collection. If *informed consent* was not obtained prior to *recovery* (e.g., *autologous tissue*, *surgical bone*) or acquisition, ~~confirmation it must occur~~ be obtained as soon as practical after *recovery* or acquisition. ~~and before use of the tissue.~~

##### **D5.212 Donor Identity**

Prior to initiation of *tissue recovery*, *collection*, or acquisition ~~procedures, at least one staff member shall verify~~ the potential *donor's* identification shall be verified with the *donor's* name as stated on the record of informed consent or *document of gift/authorization*. *Donor identity verification* shall be documented in the *donor record* prior to *tissue recovery*, *collection*, or acquisition. *Records* shall indicate the staff member(s) involved and include the source of the *verification* information (e.g., hospital wristband, medical examiner number, driver's license, or government issued identification with photograph).

(A, SB) Identification of the *donor* shall be the responsibility of the hospital staff involved with the *Autograft* ~~recovery~~.

(BT) Identification of the birth mother shall be the responsibility of the hospital staff, or the tissue bank staff member involved with acquisition.

#### **D5.300 Tissue Recovery, ~~and Collection,~~ and Acquisition —General**

Recovery, collection, or acquisition shall be performed using aseptic or clean techniques appropriate to the specific tissue type and intended use. Tissue must be labeled using a donor identifier and a description according to the SOPM (see G1.100).

### D5.310 Recovery

*Recovery shall be performed using aseptic or clean techniques appropriate to the specific tissue recovered and intended use of the tissue. The SOPM shall specify the time limits for the postmortem recovery of tissue consistent with tissue-specific standards, where applicable. If recovery is to be delayed for a deceased donor, the donor's body should be refrigerated/cooled as specified in the tissue-specific standards. To prevent cross-contamination or mix-ups, recovery from one donor shall be the exclusive activity taking place at one time at a recovery site. Other activities (e.g., embalming, autopsy, another tissue donor recovery) cannot occur simultaneously in the same room as recovery. Tissue recovery shall not occur after embalming procedures have begun (i.e., injection of embalming fluid, application of drying agents either internally or topically).*

- (LD) Methods for recovery of perioperative tissue shall be safe, aseptic, and ensure accurate identification of tissue.

### D5.320 Collection

- (R) Collection of anonymous donor semen ~~Reproductive Tissue~~ shall be made at the reproductive tissue bank using a sterile collection container. If the tissue requires transportation to the processing laboratory, it should be transported within a reasonable time period as specified in the SOPM, so as to maintain the utility of the tissue. The collection container shall be labeled with the date of collection and the donor's identification or, in the case of client depositors or directed donors, the name. The time of collection shall also be recorded. ~~If the tissue requires transportation to the Processing laboratory, it should be transported within a reasonable time period as specified in the SOPM, so as to maintain the utility of the tissue.~~

### D5.330 Acquisition

- (BT) Methods for acquisition of birth tissue shall be safe, aseptic, and ensure accurate identification of tissue post delivery.

Birth tissue shall be packaged post-delivery using a sterile receptacle/transport package in a controlled environment. Prior to acquisition, the birth tissue receptacle/transport package shall be labeled.

### D5.340 Pooling

Pooling tissue from multiple donors shall not occur during recovery, collection, acquisition or storage.

### D5.400 Time Limits for Postmortem Tissue Recovery

When recovery of tissue has begun, subsequent recovery steps must proceed without delay.

- (C, V) Cardiac tissue and vascular tissue recovery and processing time limits (i.e., warm and cold ischemic time, disinfection time, and the perfusion time [specific to vascular tissues]) shall be established by each individual tissue bank; however, the following upper time limits for initiation of recovery of specific tissue types shall not be



exceeded.

- (C) *Warm ischemic time (C) shall not exceed 24 hours from asystole if the [donor's](#) body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the [donor's](#) body was not cooled or refrigerated. If the [donor's](#) body is cooled for a period of time then not cooled for a period of time, the time period the [donor's](#) body is not cooled cannot exceed 15 cumulative hours.*
- (V) 1) *Perfusion time shall not exceed 12 hours from asystole; and*
- 2) *warm ischemic time (V) shall not exceed 24 hours from asystole if the [donor's](#) body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the [donor's](#) body was not cooled or refrigerated. If the [donor's](#) body is cooled for a period of time then not cooled for a period of time, the time period the [donor's](#) body is not cooled cannot exceed 15 cumulative hours.*

(MS, OA, S)

*The skin prep shall begin within 24 hours of asystole provided the [donor's](#) body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The skin prep shall begin within 15 hours of death if the deceased [donor's body](#) has not been cooled or refrigerated. If the [donor's](#) body is cooled for a period of time then not cooled for a period of time, the time period the [donor's](#) body is not cooled cannot exceed 15 cumulative hours.*

For expectations when evaluating ~~body-cooling~~ [of a donor's body](#), refer to Guidance Document No. 7.

### **D5.500 Recovery Environment**

All *tissue shall be recovered* in an aseptic or clean fashion using standard surgical preparation with *sterile* packs, instrumentation, and technique. Prior to *recovery*, the *recovery site must* be evaluated for suitability using pre-established criteria designed to control contamination and *cross-contamination* (see [Appendix IV AATB Guidance Document No. 2](#)). The *recovery site evaluation must* be documented, however, if the *recovery site is an operating room in a health care facility*, no documented site evaluation is required.

#### **~~D5.501~~ [D5.510](#) Recovery Site Suitability Parameters**

These *must* address the control of:

- 1) size/space;
- 2) lighting;
- 3) plumbing and drainage for the intended use;
- 4) the physical state of the facility (i.e., state of repair);
- 5) ventilation;



- 6) cleanliness of room and furniture surfaces;
- 7) pests;
- 8) traffic;
- 9) location;
- 10) other activities occurring simultaneously;
- 11) sources of contamination; and
- 12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment.

#### ~~D5.510~~ **D5.520 Recovery Cleansing and Preparation**

##### **Environment:**

An evaluation of the *recovery site* must be performed to identify potential sources of contamination (see [Appendix IV AATB Guidance Document No. 2](#)). All working surfaces (e.g., back table, Mayo stand, recovery table) used during *recovery* must be ~~disinfected~~ *decontaminated* using a bactericidal/antimicrobial agent. All cleansing and disinfecting events performed by *tissue bank* personnel *shall* be documented. For guidance, refer to [Guideline AORN's Recommended Practices for environmental cleaning in Guidelines for Perioperative Practice](#). Denver, CO: *AORN, Inc.* ~~the Surgical Practice Setting~~ (current edition).

##### **Technician:**

Technician gowning, gloving, and movement *shall* be accomplished with the same diligence as used routinely for operative procedures. Aseptic technique *shall* be followed. For guidance, refer to *AORN's Recommended Practices for Maintaining a Sterile Field* [Guideline for sterile technique](#) (current edition). Persons performing the surgical *recovery* *shall* perform a surgical scrub or wash of their hands and forearms prior to *recovery*. For guidance, refer to *AORN's Recommended Practices* [Guideline for Surgical Hand Antisepsis/Hand Scrubs](#) *hand hygiene* (current edition). A head cover, eye shields and mask *shall* be worn at the time of scrub, and a *Sterile* gown and gloves *shall* be donned after the scrub/wash. For guidance, refer to *AORN's* [Guideline](#) *Recommended Practices for surgical attire* (current edition).

##### **Donor:**

Cleansing, preparing (i.e., *skin prep*), and draping the *skin* *shall* be accomplished with the same diligence as used routinely for operative procedures. Agents used *shall* be antimicrobial *skin* preparation products, as specified in the *SOPM*, and *shall* be used in accordance with manufacturers' guidelines/instructions. For guidance, refer to *AORN's Recommended Practices* [Guideline](#) for *preoperative patient skin antisepsis* (current edition).

#### ~~D5.520~~ **D5.530 Recovery Technique**

Specific *tissue recovery* operations that control contamination and *cross-contamination* (e.g., sequencing of the *tissue recovery*, use of well-defined zone *recovery* techniques, and isolation draping in the presence of trauma; see [Appendix IV AATB Guidance Document No. 2](#)) *shall* be implemented. Areas of *skin* that have abrasions or puncture wounds *should* be avoided. All *tissue* *shall* be *recovered* using aseptic technique.

## ~~D5.521~~ D5.531 Cultures Obtained at Recovery

(MS, OA, S, SB)

If performed, the technique used to obtain cultures of *recovered tissues* shall be appropriate for the *tissue* type, and performed according to written instructions. ~~See K2.210 Pre-Sterilization/Pre-Disinfection Cultures.~~

## D5.600 Delivery Environment and Cultures Obtained Prior to Acquisition

### D5.610 Delivery Environment

(BT) If the delivery location is an operating room in a health care facility, no documented site evaluation is required, however, any other location of delivery must meet the requirements at D5.500 and D5.510. Such an evaluation must be documented.

### D5.620 Cultures Obtained Prior to Acquisition

(BT) If performed, the technique used to obtain cultures prior to acquisition shall be appropriate and performed according to written instructions.

## ~~D5.600~~ D5.700 Recovery Records

### D5.710 Recovery Records

For *allogeneic* tissue ~~other than autologous tissue~~, details of the *tissue* donation shall be documented in the *recovery record*. *Recovery records* shall include, but not be limited to:

- 1) name, and address of the *recovery* agency;
- 2) date, time and staff involved in all significant steps performed during the *recovery* (documentation shall be as per C1.100 ~~General—Records Management~~);
- 3) location and assessment of the suitability of the *recovery site*;
- 4) documentation of the *physical assessment* or *physical examination*;
- 5) documentation of any *errors*, *accidents*, or *deviations* that occurred;
- 6) donor name, age, and sex;
- 7) the type, *lot* number, manufacturer, and expiration date of *critical* reagents, supplies and materials, and the identification of equipment, used to *recover*, *rinse*, and/or transport *tissue*; and
- 8) specific *tissue recovered*; and
- 9) other available *relevant medical records*.

The *tissue bank* or agency recovering the *tissue* shall provide a *record* of the *tissue* recovered, date of *recovery*, name and address of the *recovery* agency, and name of

the *donor* to the *recovery site* facility.

(A) The following information regarding *autologous tissue recovery* shall be documented:

- 1) name and address of the institution in which the Autograft *autologous tissue* was recovered;
- 2) date and time the Autograft *autologous tissue* was recovered;
- 3) name of the physician recovering the Autograft *autologous tissue*;
- 4) *donor* name, age, sex, and hospital medical record number and/or social security number; and
- 5) type of *tissue* recovered.

#### **D5.720 Delivery and Post-Delivery Records**

Details of the delivery and post-delivery time period through *acquisition* shall be documented in the *donor's record*. These *records* shall include, but not be limited to the:

- 1) birth mother's name;
- 2) infant *donor's* gestational age;
- 3) name and address of the health care facility and the identification of the delivery environment/location;
- 4) date and time of the delivery;
- 5) the physician or other authorized practitioner involved with the delivery, or designee as permitted by law;
- 6) information to allow tracking of *critical* reagents, supplies and materials provided by the *tissue bank*;
- 7) specific *tissue(s)* acquired;
- 8) other available *relevant medical records*; and
- 9) documentation of any *errors, accidents, or deviations* that occurred.

#### **D5.700 ~~D5.800~~ Post-Recovery Packaging, Labeling, and Handling and Transport**

##### **D5.810 Post Recovery Packaging and Labeling**

Immediately following *recovery* of each individual *tissue* at the *recovery site*, *recovered tissue* shall be individually and aseptically wrapped or enclosed and shall be immediately *labeled* with the unique *donor* identifier and the description according to the *SOPM* (see G1.100). *Tissue* shall be maintained at defined environmental temperatures until the time of transport to the *processing* center. Maintenance of such temperatures shall be documented. The receptacle/transport package must be designed to prevent contamination of the contents and allow for aseptic presentation of the

tissue at the time of processing.

- (A) Immediately following *recovery* of the ~~the Autograft~~ autologous tissue, the ~~tissue~~ it shall be individually and aseptically wrapped in a manner to prevent contamination of the contents, preserve cellular structure and viability, if desired, and to allow for aseptic delivery of the specimen at time of *Processing*, if necessary, or reimplantation. The ~~receptacle~~ package shall be labeled immediately with the donor's name, age, sex, hospital medical record number and/or social security number, and institution name, definitive autologous donor identifying information such as the patient's name, hospital registration number, security number, birth date, etc., and shall be prominently labeled "FOR AUTOLOGOUS USE ONLY."
- (C) *Recovered cardiac tissue* shall be rinsed and packaged in an isotonic, sterile solution such as normal saline, lactated Ringer's solution, PlasmaLyte®, transplant organ perfusate (e.g., Belzer's UW solution, Collin's solution) or tissue culture media, immediately following *recovery*. The volume of the transport solution *should* be adequate to cover the entire heart, including the vessels and valves. The type, lot number, manufacturer, and expiration date shall be documented. ~~The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of Processing.~~
- (V) Immediately following *recovery*, *vascular tissue* shall be gently flushed and packaged in an isotonic *sterile* solution such as tissue culture media. Normal saline solution *should* not be used. The type, lot number, manufacturer, and expiration date of all reagents used for *recovery* and *packaging* shall be documented. ~~The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of Processing.~~
- (S) *Recovered skin tissue* shall be packaged in a *sterile* solution immediately following *recovery* or packaged by another method that maintains the integrity of the *tissue* for its intended use (e.g., decellularized dermis). If in solution, the volume of transport solution *must* be adequate to cover the entire *skin*. The type, lot number, manufacturer, and expiration date(s) shall be documented. ~~If in solution, the transport container must be fluid tight and designed to prevent contamination of the contents.~~

#### **D5.820 Post Delivery Packaging and Labeling**

(BT) Following delivery, tissue shall be aseptically contained. Labeling that includes a unique donor identifier and the description according to the tissue bank's SOPM (see G1.100) shall be performed prior to transport. The receptacle/transport package must be designed to prevent contamination of the contents and allow for aseptic presentation of the tissue at the time of processing.

Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such temperatures shall be documented.

#### **D5.800 D5.830 Tissue Transport ~~Transportation Following Recovery~~**

~~Following Recovery~~, *Tissue* shall be transported in a manner established by the tissue bank that permits required environmental conditions ~~to be maintained~~ for the duration of ~~transportation~~ transport necessary to maintain the integrity of the tissue for its intended use. Transportation temperatures do not require monitoring if the *packaging* and transport conditions have been *validated* to maintain the required environmental conditions, including temperatures. The ~~transportation~~ receptacle/transport package ~~containing tissue must~~ indicate that “DONATED HUMAN TISSUE” is enclosed ~~as well as~~ and ~~must~~ include the name and address of the ~~Recovery~~ originating agency and *processing* center (if different) ~~in accordance with applicable laws and regulations~~. All human *tissue processed* or shipped prior to determination of *donor suitability* eligibility ~~must~~ be under *quarantine*, accompanied by *records* assuring identification of the *donor* and indicating that the *tissue* has not been determined to be suitable for *transplantation* (e.g., “Quarantine”; “Donor Eligibility Has Not Been Completed”; and “Not Suitable for Transplant in its Current Form”).

(A) ~~Autologous tissue shall be transported to the Processing/storage center on wet ice in the time limits appropriate for the particular tissue.~~

(A, LD, CT)

When *wet ice temperatures* would be injurious to the *tissue recovered*, it may be transported at appropriate temperatures and within time limits that maintain the ~~integrity~~ quality of the *tissue* for its intended use.

(C, V) The transport ~~container~~ package shall be transported at *wet ice temperatures*. Time of acceptance of the *tissue* into the *processing* center shall be documented. *Cardiac tissue* and *vascular tissue* shall be received at the *processing* location within sufficient time following *recovery* to allow for the start of *disinfection* within the *established cold ischemic time* limit.

(MS) The *recovered tissue* shall be wrapped in an aseptic fashion with at least one moisture barrier and shall be transported at *wet ice temperatures* or colder. The maximum time that *recovered tissue* shall remain at *wet ice temperatures*, prior to either *processing* or freezing, shall be no longer than a time limit established by a validated procedure that maintains tissue quality.  
~~72 hours.~~

(OA) The *recovered tissue* shall be transported at *wet ice temperatures*. The maximum time that *recovered tissue* shall remain at *wet ice temperatures* prior to *processing* shall be no longer than ~~five days~~ a time limit established by a validated procedure that maintains tissue quality.

(S) If the *tissue* is to be *cryopreserved*, the *skin* ~~transportation container~~ transport package shall be transported at *wet ice temperatures* or *packaged* by another method that maintains the ~~integrity~~ quality of the *tissue* for its intended use.

#### **D5.900 ~~Post-Recovery~~ Reconstruction of a Deceased Donor's Body**

Unless there is a specific request from a medical examiner, pathologist, or a funeral home, the surgical incision(s) shall be closed in an aesthetic fashion and the deceased donor's body prepared for the next portion of the *recovery* or for transportation to an appropriate facility. The donor's body shall be reconstructed in accordance with the *SOPM*. ~~Donor-~~ Reconstruction *should* employ techniques consistent with funeral home guidelines and/or medical examiner or pathologist requests. Documentation of *donor* reconstruction (if

applicable) and disposition of the *donor's* body *shall* be maintained in the *donor's record*.

## **D6.000 STORAGE OF TISSUE**

Storage, including temporary storage, of recovered, acquired, or collected tissue shall be in conformance with storage temperature and monitoring expectations provided by the tissue bank that will process the tissue. See C1.300, E3.330, E3.331, and E3.340.

### **D6.100 Quarantine Areas**

Quarantine tissue storage areas including storage areas within freezers, refrigerators or other tissue storage equipment, shall be physically separated and clearly labeled as "quarantine."

### **D6.200 Segregation**

The SOPM must address when the segregation of tissue during storage is indicated and how it will be appropriately segregated to avoid contamination, cross-contamination and mix-ups.

Considerations for assessment of risk include, where applicable:

- 1) donor infectious disease test results are unavailable or this testing will not be performed;
- 2) the intended use of the tissue is primarily for transplantation or is restricted to research or education;
- 3) autologous tissue is segregated from allogeneic tissue;
- 4) the donor has been determined to be ineligible;
- 5) the ability of packaging and labeling to withstand storage temperatures, and/or
- 6) the ability to decontaminate storage equipment or the storage area should an accident occur.

Appropriate segregation must include considerations above and storage must be in clearly defined and labeled areas (shelves or compartments) of the storage equipment or storage area.

### **D6.300 Storage Equipment**

Freezers and refrigerators used for storing tissue shall be regularly maintained, calibrated, and monitored according to written QC procedures. See the series of standards at J5.000.

## SECTION E

### PROCESSING, ~~PRESERVATION, QUARANTINE, AND STORAGE~~

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

#### E1.000 RECEIPT OF TISSUE AT PROCESSING/STORAGE FACILITY

Approval or rejection of the receipt of *tissue* into the *processing* or *storage* facility *must* be documented. The receipt and movement into *storage*, to immediate *processing* or to removal, *shall* be documented, including, at a minimum:

- 1) the condition of the transport *package*;
- 2) confirmation each *tissue* is *labeled* with a *tissue identification number*, or other *traceable* unique identifier;
- 3) evidence proper environmental conditions were maintained (e.g., presence/absence of ice/coolant). [Refer to H3.300](#);
- 4) the date and time of receipt and movement; and
- 5) personnel involved.

##### E1.100 Tissue Identification

Except for *reproductive tissue*, each unit of *tissue* *shall* be assigned a *tissue identification number*, which *shall* serve to relate the *tissue* to the *donor* from whom it was *recovered* [or acquired](#) and the associated *records* at any phase [\(e.g., quarantined, unprocessed, processed inventory\)](#) of the operation. *Tissue* units *shall* be assigned the same *tissue identification number* only if they are identical and processed as a *lot*.

- (R) [Reproductive tissue donors and client depositors shall be assigned a unique identifier, which shall be used to identify the tissue during steps of collection, processing, storage, and distribution. The unique identifier can be a directed donor's or a client depositor's name. For donors and client depositors giving multiple specimens, a secondary code shall be used to distinguish between dates of collection. The reproductive tissue bank that collects and processes the reproductive tissue shall be identified by name, code, or other identifier on the final container.](#)

##### E1.200 Pooling

*Tissue* from multiple *donors* *shall* not be *pooled* during ~~recovery~~, *processing*, *preservation*, or *storage*.

#### E2.000 PROCESSING

*Processing* and *preservation* methods *shall* be *established* in accordance with *Standards* and applicable laws and regulations. All *tissue* *shall* be *processed*, *preserved*, *quarantined*, and/or *stored* pursuant to such methods so as to render them suitable for clinical use.



- (A) If *autologous tissue* is not to be *processed*, it *should* be retained in its original wrapping.
- (C, V) *Processing* shall include a *disinfection* period followed by rinsing, packaging, and *preservation*.

## **E2.100 Tissue Evaluation**

Written criteria for evaluation and assessment of *tissue quality* *must* be *established*.

(C, V, OA)

A standardized evaluation and classification system is required that describes the attributes of each *allograft*. A detailed description of the condition of the *allograft* shall be recorded in the permanent donor processing records. The *allograft* evaluation system shall be made available to the implanting surgeon.

## **E2.200 Processing Environment**

Except for *reproductive tissue*, when *tissues* are exposed to the environment during *processing*, these activities shall be consistent with the requirements of *aseptic processing*. There shall be demonstrated and documented evidence that the chosen environment achieves the *quality* and *safety* required for the type of *tissue*, *processing*, and intended use.

Without a subsequent *validated* microbial inactivation process, *aseptic processing* shall be performed in a certified and qualified bacteriologically and climate-controlled environment.

### **E2.210 Environmental Control and Monitoring**

Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of *tissue* or equipment, or accidental exposure of *tissue* to communicable disease agents, there *must* be adequate *environmental control* and monitoring of viable and non-viable particles under *dynamic* as well as *static* conditions. Effectiveness of these controls shall be *validated*. See AATB Guidance Document No. 5.

Adequate control is defined by justifying and documenting the following:

- 1) type and frequency of *environmental monitoring*;
- 2) when the samples are to be taken (e.g., during or at the conclusion of operations);
- 3) sampling locations and number of sites to be sampled;
- 4) sample duration;
- 5) sample size (e.g., surface area, air volume);
- 6) action and alert levels for test results; and
- 7) potential *corrective actions* when alert and/or action levels are exceeded.

~~(A) If *Processing* of autologous tissue is required, it shall occur in a bacteriologically and climate-controlled environment utilizing aseptic technique.~~

~~(C, V, CT)~~

~~Processing, which includes dissection, *Disinfection* and packaging of cellular, cardiac and vascular tissues, shall be performed in a certified and qualified ISO 5 (Grade A, Class 100) or cleaner laminar flow environment. Tissue shall be processed in an aseptic fashion using *Sterile* drapes, packs, solutions, instruments, and packaging material.~~

~~(MS, OA)~~

~~Tissue shall be processed in a bacteriologically and climate-controlled environment.~~

~~(S) Processing of exposed skin shall be performed in a bacteriologically and climate-controlled environment.~~

### **E2.300 Tissue Cross-Contamination**

Written *procedures* shall be prepared, *validated*, and followed for [control and](#) prevention of ~~infectious disease~~ contamination or *cross-contamination* by *tissue* during *processing*.

### **E2.400 Reagents, Supplies, Materials and Equipment**

All *critical* supplies, reagents, materials, and equipment approved for use for *processing* and *preservation* shall be identified and specifications (e.g., *sterile* where applicable) documented. It is expected that the *tissue bank* has the ability to link all supplies, reagents, materials, and equipment to *tissue processed* over the period of time they were in use.

A *record* shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, *lot* number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of staff performing the inspection. All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers' instructions.

~~(C, V, MS, OA, S, CT)~~

All non-disposable surgical instruments and mechanical/electrical equipment used in *tissue processing* shall be cleaned, [decontaminated](#) ~~disinfected~~, and, [where applicable](#) *sterilized*, between use for *tissue* from different *donors* according to written *procedures*. For non-disposable surgical instruments and mechanical/electrical equipment deemed *critical*, written *procedures* must be prepared and [methods shall](#) ~~should~~ be *validated*, to prevent contamination or *cross-contamination* during *processing*.

#### **E2.410 Stock Rotation**

Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items should be used first and not used if expired or quality is compromised.

#### **E2.420 Containers**

#### **E2.421 Physical Properties**

The *container* shall maintain its integrity, withstand *sterilization* and *storage* conditions, not produce toxic residues during *storage*, and maintain *tissue integrity and quality* for through the labeled shelf life expiration date. Containers shall not interfere with the effective use of appropriate agents applied to *sterilize* or *disinfect* the *tissue*.

If ethylene oxide is used to *sterilize processing or packaging components that come in contact with the allografts* (e.g., *disinfection jars or packaging pouches*), residues of ethylene oxide, ethylene glycol, and ethylene chlorohydrin should be evaluated. Refer to ISO 10993-7.

(C, V) Final packaging *containers* shall be adequate for use at defined *storage* temperatures and documented to remain stable and impervious to microbial particles under normal environmental conditions at the specified temperature and throughout the recommended thawing regimen.

#### **E2.422 Receipt of New Shipments**

*Containers* shall be stored under *quarantine* until the *containers* have been tested, sampled, or examined, as appropriate, and released for use. *Containers* not meeting specifications shall not be used.

#### **E2.423 Storage**

Unused *containers* shall be handled and stored to maintain integrity.

#### **E2.424 Integrity and Sterility**

*Sterilized containers* shall be handled in a manner to preclude contamination.

#### **E2.425 Visual Inspection**

Each *container* shall be examined visually for damage or evidence of contamination prior to use and immediately after filling. *Containers* not meeting specifications visual criteria shall not be used.

### **E2.500 Processing Methods**

*Tissue* shall be processed ~~by methods known to be~~ using validated methods to prevent contamination and *cross-contamination*.

#### **E2.510 Temperature Limits**

~~(C) — To prevent additional warm ischemia and potential cellular or matrix damage caused by temperature cycling, methods shall be employed that maintain the tissue and solutions during heart dissection above freezing (0°C) to 10°C. Methods/equipment shall be qualified to maintain the appropriate temperatures.~~

(C, V) Methods shall be employed that maintain the *tissue* at desired *processing* temperatures as required by reagents used and as described in written *procedures*.

- (S) If additional warm ischemia and potential cellular or matrix damage caused by temperature cycling impact integrity quality for intended use (e.g., *cryopreserved*), methods *shall* be employed that maintain the *tissue* or solutions above 10°C for no longer than 2 hours. The methods/equipment *shall* be qualified to maintain the appropriate temperatures.

#### E2.520 Time Limits for Pre-processing, Processing and Preservation Phases

Time limits and/or other valid *process control* end points or limits for the completion of each phase of *processing* and *preservation shall be established and validated with reference to tissue quality*. Additionally, a time limit and temperature for pre-processing quarantine storage that addresses tissue quality must be established and justified.

- (C, V) *Disinfection of cardiac and vascular tissue shall be accomplished via a time-specific, validated incubation and regimen process (disinfection time)*. The total ischemic time *shall not exceed 48 hours*.

~~(OA) *Processing of Osteoarticular tissue shall be completed within five days of Recovery.*~~

- (R) After collection, analysis shall be performed within an appropriate time period, examination and/or and processing, if performed, of donor semen specimens shall be initiated within a time period appropriate for retention of functional integrity quality, as specified in the *SOPM*.

- (S) When preservation of cellular viability is desired, processing of skin that is to be frozen/Cryopreserved shall be initiated within 10 days of *recovery*, provided the skin is placed in tissue storage media ~~which~~ that is replaced at least every 72 hours. If the media is not changed, *processing shall be initiated within 96 hours of recovery*.

#### E2.530 Prevention of Matrix Deterioration

(C, V, OA, S)

To prevent drying and possible cellular, ~~tissue~~, and extracellular matrix deterioration, the *tissue shall be kept moist at all times during processing using a sterile, isotonic solution/medium*. If drying does not impact integrity quality for intended use (e.g., decellularized dermis), the requirement to prevent drying is not applicable.

#### E2.540 Additives

When applicable, the type, amount, concentration, and method of incorporation/addition of all media, *cryoprotectants*, and any other additives used in *processing shall be specified in the SOPM*. This information about the *allograft shall be made available to the implanting/transplanting physician, upon request*.

#### E2.600 In-Process Controls

*In-process controls shall be applied as necessary and according to the SOPM during processing and packaging to ensure that each process meets requirements specified in the SOPM*. The *tissue*

*bank shall determine when, which, and how controls are to be performed (e.g., residual moisture testing, microbial cultures of tissue, solutions, packaging, equipment, pH measurements, or post-thaw sperm quality). Sampling for in-process controls shall be designed to be representative of the materials to be evaluated.*

*Process control procedures shall be designed to assure that tissue has the identity, characteristics, and quality intended. Procedures and any changes in these procedures shall be reviewed to ensure that such changes are verified, or where appropriate validated, before implementation.*

## **E2.610 Tolerance Limits of Processed Tissue**

*Tissue banks that process and preserve tissue shall include in their SOPM a description of the final types of tissue, any specifically required or specifically prohibited dimensions or characteristics, and the means used to assess these characteristics. At or near the end of processing, tissue shall be evaluated according to these procedures to determine whether it is in conformance with the SOPM. Relevant tissue dimensions or characteristics shall be recorded. All tissue deemed to be out of conformance shall not be released for transplantation.*

*This inspection, the staff involved, and the disposition of each tissue unit shall be documented.*

### **E2.611 ~~Specimen Sizing~~ Tissue Measurement**

~~Tissue measurement, as applicable, shall be performed according to volume or actual sizing and documented.~~

Tissue measurement shall be performed and documented and must include the quantity or other characteristics of the tissue expressed as applicable (e.g. volume, weight, dimensions, cell density, number of viable cells or a combination of these).

- (C) *Allograft heart valve grafts shall be inspected, evaluated, and sized by internal valve annulus diameter, and recorded in millimeters (mm).*

*The length of the aortic conduit, main pulmonary artery, and the left and right and left pulmonary artery arteries remnants shall be recorded in millimeters (mm) or centimeters (cm), ~~as measured along the anterior midline of each conduit.~~*

- (V) *Vascular tissue grafts shall be inspected, evaluated, and sized by diameter and recorded in millimeters (mm).*

*The length of the vascular segment shall be recorded in centimeters (cm).*

(MS, OA)

~~Specimen sizing, as applicable, shall be performed according to volume, actual measurements, or by r~~ Radiographic techniques may be used as needed.

~~(S) In addition to a unique package identification, the actual dimensions of~~

~~the contents (metric or non-metric) must be documented.~~

#### **E2.612 Calcium Residuals: Demineralized Bone**

- (MS) Unless bone is treated by a validated process to reduce minerals, representative samples of each lot shall be tested for residual calcium by a standard method.

Residual calcium content for bone labeled as demineralized shall not exceed 8% by a standard method.

For bone that has been subjected to a demineralization process with a residual calcium content target that exceeds 8% when tested, the tissue must not be labeled as demineralized and should be labeled as partially demineralized to describe the extent of demineralization.

#### **E2.620 In-House Laboratory Testing**

If the *tissue bank* performs laboratory tests and results are used to determine acceptability of *tissue* for *transplantation*, the requirements at K2.100 and K2.200 shall apply. ~~staff performing the tests shall have specific training in the procedures and shall be certified competent to perform the tests required.~~

#### **E2.621 Laboratory Records**

*Records* of in-house laboratory testing shall include, at a minimum:

- 1) sample source and quantity;
- 2) tissue identification number;
- 3) test date and identification of the person performing the test;
- 4) assay methods;
- 5) calculations, graphs, and charts, if used;
- 6) test results as well as interpretation of results;
- 7) testing or standardization of reference standards, reagents, or standard solutions; and
- 8) ~~Documentation of~~ record review by an individual other than the operator generating the *records* to ensure compliance with *Standards*.

#### **~~E2.622 Laboratory Controls~~**

~~Laboratory control procedures shall include documentation of adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.~~

#### **E2.700 Tissue Preservation/~~Cryopreservation~~**

## **E2.710 Techniques**

- (CT) ~~If tissue is to be preserved using any method, appropriate protocols shall be validated with respect to cell Quality.~~
- (C, V) ~~The Allograft shall be removed from the Disinfectant solution then rinsed in a disinfectant free solution. If tissue is to be Cryopreserved it will be packaged with a Cryoprotectant medium then frozen at a steady, controlled, predetermined rate with compensation for heat of crystallization/latent heat of fusion. The tissue shall be frozen at a specific rate to a predetermined specific end point. If tissue is to be preserved using other methods, appropriate protocols shall be validated with respect to tissue integrity.~~
- (S) ~~When the tissue is to be cryopreserved, freezing of skin shall be done in a manner that ensures a slow cooling rate to maintain the structural integrity of the skin. Variable rate cooling using insulated heat sink boxes or programmed control rate freezing techniques are acceptable methods of skin Cryopreservation. When programmed control rate techniques are utilized, they must allow the tissue to freeze at a steady, predetermined rate with heat of crystallization compensation. The tissue shall be frozen at a specific rate to a predetermined specific end point, not warmer than -40°C.~~

## **E2.710 Lyophilization**

(MS) ~~Validated procedures for lyophilizing musculoskeletal tissue shall be established and described in the SOPM. Each lyophilization cycle shall be monitored and recorded for shelf temperature, condenser temperature, and vacuum; values shall be recorded daily. Residual moisture measurement shall not exceed a limit linked to tissue quality. The analytical method selected must be validated for its intended use. Additionally, each lyophilization cycle shall document, if applicable, the method/length of Disinfection of the tissue. Residual moisture analysis shall not exceed 6% of initial weight by gravimetric or Karl Fischer analysis or 8% by nuclear magnetic resonance spectrometry (NMR). The final container shall maintain these moisture requirements for the indicated expiration period.~~

## **E2.720 Dehydration/Desiccation**

(MS) ~~Validated procedures for dehydration or desiccation of musculoskeletal tissue shall be established and described in the SOPM. Temperature shall be monitored during each Dehydration cycle, and shall not exceed the maximum temperature for Dehydration. Quality control parameters shall be established and verified for each batch.~~

If a residual moisture limit has been established for finished tissue, the container shall maintain the limit for the duration of the expiration period. The residual moisture level shall not exceed a limit linked to tissue quality. The analytical method selected must be validated for its intended use.

## **E2.730 Freezing Tissue**

- (CT) ~~If tissue is to be frozen/cryopreserved, a specific freezing rate to a predetermined specific end point must be selected. When applicable, procedures for freezing shall be established and the method controlled to maintain cell Quality.~~



~~(MS)~~—Procedures for freezing ~~musculoskeletal and soft-tissue~~ shall be established and documented to maintain tissue quality.

~~(R)~~—Procedures for controlled rate freezing of embryos shall be established. Freezer chamber temperature shall be monitored during each freezing cycle. The thermal profile for each vial or *Batch* shall be logged with the specimen records.

## **E2.740 Cryopreservation**

Except for reproductive tissue, tissue to be cryopreserved must be frozen at a controlled and monitored, predetermined rate with compensation for heat of crystallization/latent heat of fusion to a predetermined end-point. Documentation of the concentrations of cryoprotectant and nutrient or isotonic solutions in the cryopreservative solution shall be maintained. When applicable, procedures for cryopreservation shall be established and the method controlled to maintain tissue quality.

~~(R)~~ Procedures for ~~controlled rate freezing of embryos~~ cryopreservation of reproductive tissue shall be established and documented. ~~Freezer chamber temperature shall be monitored during each freezing cycle. If a controlled rate chamber is being utilized,~~ the thermal profile for each vial or *Batch* cryopreservation cycle shall be logged with the specimen records.

~~(OA, MS, CT)~~

~~Procedures for the Cryopreservation of tissue shall be established and documented. Documentation of the concentrations of Cryoprotectant and nutrient or isotonic solutions in the cryopreservative solution shall be maintained.~~

## **E2.741 Control-Rate Freezing: Surrogate Packages**

~~(C, V)~~—If freezing surrogates are used for monitoring the freezing program, the packaging shall be regularly inspected and solutions and tissue changed when indicated. Monitoring for deterioration of the packaging shall be performed. The processing center shall have a procedure describing the assembly of such surrogates and a means for monitoring ~~the surrogates~~ their integrity.

## **E2.742 Termination of Freezing Program**

~~(C, V, S)~~

Upon termination of the freezing program, the *cryopreserved tissue* shall immediately be placed in *storage*. Temperature fluctuation and cycling should be avoided.

## **E2.743 Freezing Profile**

~~(C, V, S)~~

If a programmed control-rate freezing method is employed, a *record* of the freezing profile shall be evaluated and approved and become a permanent part of the *processing records*.

## **E2.750 Chemical Preservation**

(BT, MS)

*Procedures for the preservation of musculoskeletal tissue by chemical means shall be validated and documented. When chemical preservation has been used, the package insert shall so indicate.*

## **E2.800 Sterilization/Disinfection of Tissue**

Individual *processing* facilities shall establish, validate, and document *disinfection* or *sterilization* regimens and microbial surveillance methods. The *SOPM* shall establish a list of organisms that necessitate discard, *sterilization* and/or *disinfection* of *tissue*. The list shall be based upon not only the category type of *tissue* but also the method by which the *tissue* was processed (e.g., *cryopreserved MS tissues* that cannot be *sterilized* and can only be *disinfected* and rendered culture negative).

The following are considered to be pathogenic, highly virulent *microorganisms* that shall result in tissue discard unless treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms:

(C, V, CT)

- 1) *Clostridium* ~~fungi (yeasts, molds)~~ ;
- 2) ~~*Clostridium*~~ fungi (yeasts, molds); and
- 3) *Streptococcus pyogenes* (group A strep.).

(S) ~~The following are considered to be pathogenic, highly virulent *Microorganisms* that result in tissue discard unless treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms:~~

- 1) *Clostridium* ~~*Staphylococcus aureus*~~;
- 2) *Enterococcus* sp. ~~*Streptococcus pyogenes* (group A strep.)~~ ;
- 3) fungi (yeasts, molds) ~~*Enterococcus* sp.~~ ;
- 4) gram negative bacilli;
- 5) *Staphylococcus aureus* ~~*Clostridium*~~ ; and
- 6) *Streptococcus pyogenes* (group A strep.) ~~fungi (yeasts, molds)~~ .

(MS, OA)

- 1) *Clostridium*; and
- 2) *Streptococcus pyogenes* (group A strep.).

## **E2.810 Non-Terminal Irradiation**

A dose is selected to reduce or eliminate *bioburden*. The selected dose *shall* be justified and any *claims* made *must* be supported by data. The type of irradiation *shall* be indicated

on the *container label* or *package insert* of all *tissue* exposed to *non-terminal irradiation*.

## E2.820 Terminal Sterilization by Irradiation

The most common sources of ionizing radiation are Cobalt 60, electron beam, and X- ray. Identification of the irradiation source, the dosimetry, and completed certificate of irradiation *shall* be documented in the *processing record*. The *sterilization* dose used *must* be *validated* and supported by data. A *sterility assurance level* (SAL) *shall* be selected and the *sterilization* dose *must* be shown to be capable of achieving that SAL.

*Validation* methods ~~used may include, but are not limited to, Biological Indicators (BIs)~~ generally are *bioburden*-based methods (e.g., AAMI/ISO 11137), ~~or it may be based on a group of pre-selected organisms~~ but other methods can be justified. The type of irradiation *shall* be indicated on the *container label* or *package insert* of all *tissue* exposed to irradiation.

## E2.830 Sterilization by Other Methods

*Tissue sterilization* by other methods (other than by irradiation) *shall* be documented in the *processing record*. This includes the type of *sterilization*, the *processing* parameters, and certification of *sterilization*. The *process* utilized to *sterilize* the *tissue* *must* be *validated* and supported by data. A *sterility assurance level* (SAL) *shall* be selected and the method *must* be shown to be capable of achieving that SAL. *Validation* methods ~~used may include, but are not limited to, Biological Indicators (BIs) (e.g., AAMI/ISO 11135),~~ generally are *bioburden*-based methods (e.g., AAMI/ISO 11137), ~~or it may be based on a group of pre-selected organisms~~ but other methods can be justified. The type of *sterilization* method used *shall* be indicated on the *container label* or *package insert* of all *tissue* exposed to the method.

Following ethylene oxide *sterilization*, *procedures* *shall* be *established* to ensure appropriate aeration has eliminated residual ethylene oxide and/or its breakdown products.

Residual Level in Parts per Million			
Tissue Size/Weight	Ethylene Oxide	Ethylene Chlorohydrin	Ethylene Glycol
Very Small (<100 mg)	2,500	2,500	5,000
Small (<10 grams)	250	250	5,000
Medium (10–100 grams)	100	100	2,000
Large (>100 grams)	25	25	500

## E2.840 Disinfection by Chemical Agents

(MS) Iodophors, ethanol, and other solvent/detergent combinations *may* be used as *disinfectants* of bone in a *validated processing procedure*. ~~The following shall not be used (except for ear drums and ear ossicles): mercurials, quaternary compounds, formaldehyde, beta propiolactone, glutaraldehyde, and chloroform.~~ In any instance where a chemical *disinfectant* or antibiotic agent is used, the *container label* or *the package insert* shall be labeled as to identify presence of possible trace residuals. Refer to G3.120.

## **E2.850 Other Disinfection Agents**

(BT, MS)

Other agents such as heat, ultraviolet radiation, or exposure to antibiotics *may* be used as *disinfection* agents. *Procedures* for *processing* with such agents *shall* be documented and *validated* to ensure consistency in *tissue processing*.

## **E2.900 Processing and Preservation Records**

A *record* *shall* be created to document the *processing* and *preservation* of *tissue*. *Processing* and *preservation records* *shall* include the following:

- 1) *processing* dates and responsible *processing* personnel;
- 2) *tissue identification number(s)* and type(s) of *tissue* being *processed*;
- 3) *tissue* measurements (e.g., weight, dimensions, volume), as appropriate;
- 4) *expiration*, where applicable;
- 5) *type* and quantity of *tissue* sampled for *in-process controls*;
- 6) *final disposition* of each *tissue* obtained and/or *processed*; and
- 7) *the type*, *lot number*, manufacturer (unless *recorded* in other *records*), and expiration date, where applicable, of *critical* reagents, supplies and materials, and the identification of *critical* equipment, used to *process* and/or *preserve tissue*.

## **E3.000 STORAGE**

### **E3.100 ~~Quarantining~~ Quarantine**

#### **E3.110 Quarantine Areas**

*Quarantine tissue storage* areas including *storage* areas within freezers, refrigerators or other *tissue storage* units, *shall* be physically separated and clearly *labeled* to distinguish *quarantine tissues* from *tissues* not suitable for *transplant* and from *tissues* available for *distribution*.

#### **E3.120 Situations Requiring Quarantine**

Human *tissue* *shall* be *quarantined* until the *tissue* is either determined to be suitable for *processing*, *transplantation* or *another* appropriate *disposition* is accomplished. All *tissue* *shall* be *quarantined* until the following criteria for *donor suitability* *eligibility* are satisfied:

- 1) *all* required infectious disease testing has been completed, reviewed by the *responsible person*, and found to be negative or non-reactive; and
- 2) *donor* screening has been completed, reviewed by the *responsible person*, and determined to indicate freedom from risk factors for and clinical evidence of HIV,

hepatitis B, and/or hepatitis C infection.

(R) ~~Cryopreserved Reproductive Tissues from untested Client Depositors shall be stored in a physically separate area clearly defined from those of tested Client Depositors. Tissues from Client Depositors known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the Reproductive Tissue Bank's Medical Director shall be stored in a physically separated area clearly identified from tissue of seronegative Client Depositors. See F2.200 for documentation required for release.~~

*Tissue shall be quarantined at any phase of the operation when its release could affect the safety, effectiveness, or quality of the tissue, and subsequently, the health of the recipient. The following tissue shall be quarantined:*

- 1) *tissue* that is pending completion of *processing*, *packaging*, *preservation*, or *labeling* and final-release-approval *signature*;
- 2) *tissue* *recovered*, *collected*, or *acquired* from *donors* not meeting *established donor suitability eligibility* criteria, including unacceptable test results;
- 3) *tissue* involved in a *recall* pending investigation, documentation, and *resolution*;
- 4) *tissue* failing to meet technical or *quality assurance* specifications;
- 5) *tissue* pending discard as medical waste; and
- 6) *tissue* returned by a *consignee*, pending evaluation.

### **E3.130 Labeling Quarantined Tissue**

All human *tissue processed* or shipped prior to determination of *donor suitability eligibility* must be under *quarantine*. Such *tissue* shall be accompanied by *records* assuring identification of the *donor* and indicating that the *tissue* has not been determined to be suitable for *transplantation*. *Tissue* determined to be unsuitable for *transplantation* and intended for release for other purposes shall be identified accordingly.

### **E3.140 Quarantine Records**

*Quarantine records* for *tissue quarantined* post-release shall indicate the reason for *quarantine* and the final *disposition* of the *tissue*. Release dates or disposal dates shall be indicated as well.

### **E3.200 Segregation of Tissue**

The SOPM must address whether the segregation of tissue during storage is indicated and how it will be appropriately segregated to avoid contamination, cross-contamination and mix-ups.

Except for reproductive tissue, considerations for assessment of risk include, where applicable:

- 1) donor infectious disease test results are unavailable or this testing will not be performed;

- 2) the intended use of the *tissue* is primarily for *transplantation* or is restricted to research or education;
- 3) *autologous tissue* is segregated from *allogeneic tissue*;
- 4) the *donor* has been determined to be ineligible;
- 5) the ability of *packaging* and *labeling* to withstand *storage* temperatures; and/or
- 6) the ability to *decontaminate storage* equipment or the *storage* area should an *accident* occur.

Appropriate segregation *must* include considerations above and *storage must* be in clearly defined and labeled areas (shelves or compartments) of the *storage* equipment or *storage* area.

- (A) ~~Autologous tissue, for which a donor's sample tests positive or reactive for infectious diseases, should be appropriately segregated during storage.~~
- (R) ~~Procedures for storage of tissues from *Client Depositors* or *Directed Donors* whose test results are positive or repeatedly reactive must be established and maintained.~~  
*Cryopreserved reproductive tissues* from untested *client depositors* shall be stored in a physically separate area clearly defined from those of tested *client depositors*. *Tissues* from *client depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the *reproductive tissue bank's* Medical Director shall be stored in a physically separated area clearly identified from *tissue* of seronegative *client depositors*. See F2.200 for documentation required for release.

### **E3.300 Storage Temperatures**

Each *tissue bank* shall establish acceptable temperature-range limits for the *storage* of *tissue* ~~at each phase of the operation~~ before and after *processing* in accordance with these *Standards*, applicable laws and regulations and in consideration of *tissue quality* and the *packaging system* for the *tissue*.

- (A) *Storage* temperatures and conditions shall be the same as for comparable *allogeneic tissue*. Any exception shall require written approval of the Medical Director of the *tissue bank*.
- (CT) ~~Procedures for storing cells should be established and methods controlled to maintain or preserve cell *Quality*.~~

### **~~E4.110 Refrigerated Tissue~~**

- (OA) ~~Procedures for storing refrigerated musculoskeletal tissue to assure tissue viability shall be written. Refrigerated musculoskeletal tissue shall be recovered aseptically and placed in an isotonic or nutrient medium with suitable antibiotics at 1°C to 10°C. If any additional *Processing* of refrigerated musculoskeletal tissue is necessary, the total wet ice/refrigeration time should be no longer than 5 days from *Recovery*.~~
- (S) ~~Refrigerated skin shall be stored at temperatures above freezing (0°C) to 10°C.~~

~~Refrigerated skin shall be stored in a refrigeration system that is monitored, with a permanent record made of the temperature.~~

### E3.310 Frozen and Cryopreserved Tissue

(MS, OA)

*Procedures for storing processed frozen and cryopreserved tissue to ensure graft safety and ~~function~~ quality shall be written. Processed frozen or cryopreserved musculoskeletal tissues shall be stored at temperatures of -40°C or colder.*

*Temporary storage of processed frozen or cryopreserved musculoskeletal tissue between -20°C and -40°C is limited to six months total; ~~and grafts stored at this temperature range must then be transferred to -40°C or colder, used or discarded.~~*

(C, V) *Cryopreserved cardiac tissue and vascular tissue allografts shall be maintained at temperatures of -100°C or colder.*

(R) *Reproductive tissues shall be stored either in liquid nitrogen or in the vapor phase of liquid nitrogen.*

(S) *Frozen or cryopreserved skin shall be stored at ultra-low (-40°C or colder) temperatures.*

### E3.320 Lyophilized/Dehydrated/Desiccated Tissue

~~(MS)~~ *Lyophilized, ~~or dehydrated,~~ or desiccated tissue must be stored at ambient temperature or colder.*

### E3.330 Monitoring Storage Temperatures

A temperature monitoring system *shall* be utilized to document temperatures and to alert staff when temperatures have strayed outside acceptable limits. *Procedures shall* be in place for reviewing temperatures. Documentation of such review *shall* be indicated with the reviewer's initials and the date. If temperature *recording* charts are used, they *shall* be initialed and dated when placed on and also when removed from the *storage* unit. Completed charts *shall* be retained for the duration specified in C1.300. If *storage* utilizes liquid nitrogen, either liquid nitrogen levels or temperature *shall* be monitored and documented at an interval specified in the *SOPM*.

### E3.331 Storage Conditions for Commonly Transplanted Human Tissue

~~Cardiac tissue includes, but is not limited to, *Valved Conduits, Non-Valved Conduits, and Patch Grafts*; vascular tissue includes, but is not limited to, *Arterial Grafts and Vein Grafts*; musculoskeletal tissue includes, but is not limited to, bone and cartilage, and soft tissue such as tendon, ligament, nerve, fascia, pericardium, amniotic membrane, chorionic membrane, peritoneal membrane, adipose tissue, and *Dura Mater*.~~

Storage Conditions for Commonly Transplanted Human Tissue		
Human Tissue	Storage Conditions	Temperature (°C) *
<u><i>Birth tissue (BT)</i></u>	<u><i>Frozen, refrigerated, cryopreserved, lyophilized,</i></u>	<u><i>Established by the tissue bank</i></u>



	<u>dehydrated, desiccated</u>	
Cardiac (C), vascular tissue (V)	Frozen, cryopreserved	-100°C or colder
Cellular tissue (CT)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, cryopreserved	Established by <u>the tissue bank</u>
Musculoskeletal tissue (MS), osteoarticular graft (OA)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, cryopreserved <del>and non-eryopreserved</del> (temporary storage for 6 months or less)	-20°C <u>or colder</u> to -40°C ( <u>this is warmer than -40°C but colder than -20°C</u> )
	Frozen, cryopreserved <del>and non-eryopreserved</del> (long term storage)	-40°C or colder
	<u>Lyophilized, dehydrated, desiccated</u>	Ambient **
Reproductive tissue (R)	Frozen, cryopreserved	LN <sub>2</sub> (Liquid or Vapor Phase)
Skin (S)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, cryopreserved	-40°C or colder
	<u>Lyophilized, dehydrated, desiccated</u>	Ambient **
* Warmest target temperature unless noted to be a range		
** Ambient temperature monitoring not required for <u>lyophilized, dehydrated, or desiccated tissue</u>		

### E3.340 Emergency Transfers

Policies and *procedures shall* be developed for the emergency transfer of *tissue* to designated alternative *storage* facilities and for alternative monitoring methods in the event of mechanical failure or loss of coolant. These *shall* include specification of *tolerance limits* or temperatures and time limits after which the initiation of the emergency transfer is required. Actions to be taken when limits have been exceeded *shall* also be specified in the *SOPM*.

### E3.400 Expiration Date/Storage Period

The maximum *storage* period for *tissue shall* be appropriate to the type of *tissue*, method of preservation, required *storage* temperature, *packaging*, and *processing*, as well as to its intended application. Expiration dates ~~should~~ *shall* be qualified to demonstrate that the *packaging system or container* is suitable to maintain ~~product integrity~~ tissue quality (e.g., sterility, moisture content) ~~for the entire shelf life~~ through the expiration date.

- (A) The implanting physician *shall* be informed of any expiration dates.

### E3.410 Refrigerated Tissue

(MS, OA)

~~The expiration time of refrigerated musculoskeletal tissue shall be 5 days from the date of Recovery or established in the SOPM using a validated method for determining expiration dating.~~

- (S) Autologous skin that has not been *processed* or *preserved shall* should be stored

refrigerated for no longer than 14 days. NOTE: This standard is currently under review.

#### **~~E4.220 Frozen and Cryopreserved Tissue~~**

~~(MS, OA)~~

~~Expiration dates of frozen and frozen *Cryopreserved* tissue shall not exceed five years from the date of *Processing* unless a longer expiration date has been validated. NOTE: This standard is currently under review.~~

~~(C, V) Each tissue bank shall determine a maximum storage period allowable for grafts to be distributed. Limitations imposed by packaging, or by anticipated untoward effects of long term storage on tissue characteristics related to function, shall be validated and taken into account.~~

#### **~~E4.230 Lyophilized/Dehydrated Tissue~~**

~~(MS) Expiration dates of *Lyophilized* or dehydrated tissue shall not exceed five years from the date of initial *Processing* unless a longer expiration date has been validated. NOTE: This standard is currently under review.~~

#### **~~E1.031 Documentation of Tissue Condition~~**

~~(C, V) A detailed description of the condition of the *Allograft* shall be recorded in the permanent donor *Processing* records. Records shall be made of any observed tissue abnormalities and/or imperfections.~~

#### **~~E1.400 Tracing of In-Process Tissue~~**

~~There shall be a means to identify and trace tissue at all times at any phase (e.g., *Quarantined*, unprocessed, processed inventory) of *Processing*.~~

## SECTION F

### ~~RELEASE AND TRANSFER OF TISSUE~~ RELEASE

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

#### **F1.000 TISSUE RELEASE—~~GENERAL REVIEW REQUIREMENTS~~**

Prior to release of *tissue* for *transplantation*, the Medical Director or licensed physician designee shall determine donor eligibility. All necessary information *shall* be complete and compiled in a standardized format prior to final review and determination of *donor suitability* eligibility and *tissue* acceptability for *transplantation*. Each *donor record* *shall* contain a *disposition*/release statement and *signature* of both the Medical Director or licensed physician designee who is assuming responsibility for *donor suitability* eligibility determination and, if different, the individual(s) responsible for reviewing all technical and *quality control* specifications. If *processing* was performed, there *shall* be documentation of a review by designated personnel of all technical and *quality control* specifications. An *SOPM* *shall* clearly define the responsibilities of each reviewer.

##### **F1.100 Donor ~~Suitability~~ Eligibility Review**

The eligibility of each *donor* shall be determined by the Medical Director or licensed physician designee upon review of all *records* as specified below and in accordance with the *SOPM*.

Although the *donor risk assessment interview* may be preliminarily reviewed by technical staff to evaluate acceptability for *recovery*, *acquisition*, *collection*, or *processing*, *tissue* *shall* not be released for *transplantation* without determination of *donor suitability* eligibility by the Medical Director or licensed physician designee.

##### **F1.110 Records for Review**

The Medical Director or licensed physician designee shall determine donor eligibility based on a review and evaluation of the *donor's relevant medical records* or a summary of these generated by a trained individual. The determination of eligibility shall be based on the *SOPM*, these *Standards* and applicable laws and regulations. The *donor suitability* eligibility review *shall* include, but is not limited to these records:

- 1) acceptability of the *authorization* or *informed consent*;
- 2) suitability of the *recovery site*, delivery environment, or where *collection* took place;
- 3) pertinent information from the *medical records* generated at the time of death, including any pathology and laboratory reports, physician summaries, and transfusion/infusion information;
- 4) *the donor risk assessment interview*;
- 5) all results of laboratory testing relevant to *donor suitability* eligibility;
- 6) any plasma dilution calculations used to determine the acceptability of the blood sample used for testing;

- 7) all relevant culture results up to and through the completion of *recovery* (e.g., blood cultures, if performed; *pre-sterilization/pre-disinfection cultures*, if available);
- 8) applicable time limits for *tissue recovery*;
- 9) pertinent circumstantial and *donor* screening information relayed to *tissue bank* staff;
- 10) results of the *physical assessment* or *physical examination*;
- 11) the autopsy report, or a summary of findings, if an autopsy was performed; and
- 12) any other information gathered for the purposes of disease screening as required by *Standards* and applicable laws or regulations.

In the case of pediatric *donors* who have been breastfed within the past 12 months and/or are 18 months of age or less, the birth mother's risk for transmissible disease *shall* be evaluated for HIV, HBV, HCV and other infectious agents when indicated. See Appendix II.

For all *donors* one month (28 days) of age or less, the infant and the birth mother *shall* be screened for risk of relevant communicable disease agents and diseases (RCDAD) and the mother's blood *must* be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.

Once the determination is made, the ~~suitability~~ donor eligibility statement *shall* be documented, dated, and signed by the Medical Director or licensed physician designee.

#### **F1.111 Absence of Third Party Records**

When no *third party records* are available that can be used to establish a likely cause of death, and if no autopsy was performed, a *certified copy* of the death certificate *must* be included in the *donor record*. If it is not possible to obtain a *certified copy*, a *verified copy* of the death certificate *must* be included in the *donor record*.

When *third party records* are available that can be used to establish a likely cause of death, or if an autopsy was performed, obtaining a *certified copy* or *verified copy* of the death certificate is voluntary.

#### **F1.112 Autopsy Report**

If an autopsy was performed, the *tissue bank's* Medical Director or licensed physician designee *shall* review the autopsy report or a summary of findings prior to the release of *tissue* to inventory. If a copy of the autopsy report is not available for the *donor's record*, the cause of death and other pertinent autopsy findings *shall* be documented in the *donor's record*.

If it is determined that an autopsy was not performed due to infectious disease risk or, if an autopsy was performed, if any special precautions were taken that would suggest risk of a communicable disease in the *donor*, this information *should* be considered.

In the case of suspected Sudden Unexpected Infant Death (SUID), an autopsy *should* be performed and results reviewed to confirm the cause of death.

(DM) After the *dura mater* has been recovered, a qualified pathologist *shall* perform an examination of the *donor's* brain. Following fresh examination, the brain *should* be fixed and sliced, gross examination of the entire brain *should* be conducted (including multiple cross sections), and multiple specimens of *tissue should* be obtained (from different parts of the brain, e.g., frontal and occipital lobes) for histological examination. The gross and histologic findings *must* be assessed for any evidence suggestive of transmissible spongiform encephalopathy (TSE).

#### **F1.120 Infectious Disease Risk Review**

*Tissue shall not be distributed from a donor who, or a donor whose birth mother, has engaged in behaviors defined as high risk for transmission of relevant communicable disease agents or diseases (RCDADs). This information shall be obtained via a donor risk assessment interview, physical assessment or physical examination, and by review of other available relevant medical records.*

The Medical Director or licensed physician designee *shall* not determine an *allogeneic donor* eligible with any of the following findings:

- 1) evidence of significant active infection at the time of donation for *relevant communicable disease agents or diseases* (RCDADs). These include, but are not limited to: septicemia, viral disease (e.g., HIV, viral hepatitis, West Nile virus, rabies, Ebola virus disease, Zika virus infection, etc.), human transmissible spongiform encephalopathies, untreated syphilis, clinically active tuberculosis, leprosy (Hansen's disease) or systemic mycosis; and/or
- 2) risk factors for *relevant communicable disease agents or diseases* (RCDADs) as specified in Appendix II.

(R) *Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the semen. For all reproductive tissue donors, there shall not be evidence of infection within the past twelve months with Chlamydia trachomatis and/or Neisseria gonorrhea unless the reproductive tissues are collected by a method that ensures freedom from contamination of the tissue by infectious disease organisms that may be present in the genitourinary tract.*

#### **F1.130 Other Medical Conditions**

In addition to the infectious disease risk review, the Medical Director *shall* establish criteria and evaluate *tissue donors* for conditions that may adversely affect the *safety* or *utility* of the specific types of *tissue processed* and/or *distributed* by the *tissue bank*. Such conditions include, but are not limited to:

- 1) history of autoimmune diseases;
- 2) current or prior diagnosis of malignancy and the evaluation *shall* include the type of malignancy, clinical course, and treatment prior to acceptance;
- 3) ingestion of, or exposure to, toxic substances;

- 4) genetic, metabolic, traumatic, or infectious diseases that may adversely affect the quality of specific tissues;
- 5) previous surgery; and
- 6) diseases of unknown etiology.

#### **F1.140 Interpretation of Infectious Disease Test Results**

Disposition of allogeneic tissue shall be based upon the interpretation of all infectious disease test results and shall be as follows:

- 1) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive on an FDA-licensed, approved, or cleared donor screening test for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, or anti-HCV. When a birth mother's specimen is used for testing, these same rules apply.
- 2) Viable leukocyte-rich tissue (e.g., semen) shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive (RR) on an FDA-licensed, approved, or cleared donor screening test for anti-HTLV-I or anti-HTLV-II.

The eligibility of other human tissue for transplantation from donors whose specimens test RR for anti-HTLV-I or anti-HTLV-II shall be determined by the Medical Director.

Note: Law and/or regulation, including, where applicable, foreign laws and/ or regulations, may differ in regard to a RR HTLV antibody test result and how this impacts the suitability of the donor's tissues for transplantation.

- 3) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen had a final test result of positive, repeat reactive, or repeatedly reactive on a screening test using a NAT assay. When a birth mother's specimen is used for testing, these same rules apply.
- 4) If a laboratory that performs organ donor testing performs the initial testing in duplicate or triplicate, the tissue bank must obtain and review the results of all individual tests performed. If any one of those initial tests is reactive or positive, the tissue shall be determined not suitable for transplantation.
- 5) Tissue from a donor reactive for syphilis using an FDA-licensed, cleared, or approved **non**-treponemal screening assay may be used for transplantation only if the sample is found to be negative using an FDA-licensed, cleared or approved treponemal-specific confirmatory assay. If initial testing was performed using an FDA-licensed, cleared, or approved treponemal-specific assay and was reactive, the tissue shall not be used for transplantation.
- 6) If results of additional infectious disease testing are received for tests that are not required, such test results must be included in the donor's record and any results from those tests must be considered when determining donor eligibility. Procedure(s) shall be established for the interpretation of additional infectious disease test results.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority regarding test kit licensing/approval apply.

- (A) Determination of the final *disposition of tissue* in which a *donor's* blood sample tests positive is the responsibility of the *autologous donor's* physician. If *tissue* from a *donor* who tests positive is to be stored in a *tissue bank*, refer to E3.200.
- (R) Determination of the use of *client depositor* and/or *directed donor reproductive tissues* in cases where required test results are positive or repeatedly reactive *must* be documented according to protocols described at F2.200 (see note for CMV below).

*Tissue* from an *anonymous semen donor* who tests reactive for an active, acute infection with cytomegalovirus (CMV) *shall* not be deemed suitable for use. *Tissue* from an *anonymous semen donor* determined to be in a latent CMV status *may* be acceptable. Each *reproductive tissue bank* *shall* develop a *procedure* for determining eligibility for both *anonymous* and *directed donors*. *Procedures must* also include provisions for communicating CMV status to the *end-user physician* such that a decision can be made regarding use of *tissue* from a CMV positive (total IgG plus IgM) *donor*.

*Tissue* from a *donor* testing positive for *Chlamydia* or *Gonorrhea* *shall* not be suitable for use.

## **F1.200 Technical Review**

*Tissue* may be released for *transplantation* only with notation in *processing records* by *responsible persons* ~~processing technicians or their supervisor~~ that *tissue* produced meets technical specifications set forth in the *SOPM* (e.g., dimensions, quality) and that *processing* was performed according to the *SOPM*. There *must* be a *signature* by technical staff indicating that all technical elements were reviewed.

For contractual *processing* arrangements, *tissue shall* be released for *transplantation* by the distributing *tissue* bank only with a *signature* and written *disposition/release* statement or equivalent documentation from the *processing* center indicating that all *quality* ~~Quality Assurance and Control~~ measures were reviewed and determined to be acceptable according to the written *SOPM*. The written *disposition/release* statement or equivalent documentation *shall* indicate that the following conditions, at a minimum, have been met:

- 1) review of *tissue* processed for consistency with specific *tissue* requirements;
- 2) review of all *processing* and packaging bacteriologic testing results for completeness and acceptability;
- 3) review for completeness and acceptability of any test or environmental testing results generated;
- 4) review of all *lot* numbers and expiration dates *recorded* for *verification* of completeness and that all were within acceptable ranges (e.g., recovery kits, culture media, *processing* solutions);
- 5) review of all *processing records* for completeness and accuracy, and *verification* that *tissue*



was *processed* in accordance with the *SOPM* and met defined specifications;

- 6) *review* and comparison of *tissue* obtained and units produced from each *tissue* for *verification* that the *disposition* of each *tissue recovered*, *acquired*, or *collected* is *traceable*;
  - 7) *verification* that all (if any) *error* and *accident* reports potentially related to the *safety* or quality of the *tissue* to be released are resolved and *corrections* made where appropriate;
  - 8) *verification* that all *processing* was accomplished within time limits specified in the *SOPM* and within applicable technical specifications in the *SOPM* (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves); and
  - 9) *if tissue* was recovered or collected by another entity, *verification* that the shipment was acceptable when it arrived at the *processing* center (e.g., with respect to temperature and time limits).
- (A) If *autologous tissue* is *processed*, the *autograft* may be released for *clinical use* ~~*transplantation*~~ only upon notation in *processing records* by technicians or their supervisor that *processing* was performed according to the *SOPM*. There *must* be a *signature* by technical staff indicating that all technical elements were reviewed.

#### **F1.300 Quality Assurance/Quality Control Review**

Except for *reproductive tissue*, *tissue* shall *not* be released for *transplantation* ~~*only with*~~ *without* a documented *signed* *disposition/release* statement from the *responsible person(s)* ~~*person responsible for authorizing release*~~ at the site of *distribution*, indicating that, at some time prior to release, all *quality* ~~*Quality Assurance and Control*~~ measures were performed and found acceptable according to the written *SOPM*. The written *disposition/release* statement or equivalent documentation *shall* indicate that the following conditions, at a minimum, have been met:

- 1) *review* of *tissue processed* for consistency with specific *tissue* requirements;
- 2) *review* and comparison of *tissue* obtained and grafts produced from *tissue* for *verification* that the *Disposition* of *tissue recovered* is *traceable*;
- 3) *verification* that all (if any) *error* and *accident* reports, potentially related to the *safety* or quality of the *tissue* from each *donor*, are resolved and *corrections* made where appropriate;
- 4) *verification* that all *processing* was accomplished within time limits specified in the *SOPM* and within applicable technical specifications in the *SOPM* (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves);
- 5) *if tissue* was *recovered* by another entity, *verification* of the acceptability of the shipment upon arrival at the *processing* center (e.g., with respect to temperature and time limits);
- 6) *verification* that the Medical Director or licensed physician designee has made a decision regarding *donor suitability* *eligibility* and that all directives of the Medical Director regarding the *donor* were implemented.
- 7) *verification that final labeling of tissue was performed in accordance with SOPM and*

### Standards.

- (R) *Reproductive tissue shall not be released for clinical use without a signed, written disposition/release statement of the person responsible for authorizing release, at the site of processing, indicating that all quality ~~Quality Assurance and Control~~ measures were reviewed and found acceptable according to the written SOPM. This includes, but is not limited to:*
- 1) *review of donor age and of tissue processed for consistency with specific tissue requirements;*
  - 2) *record and verification that all lot numbers and expiration dates were complete and that all were within acceptable ranges (e.g., cryopreservation media);*
  - 3) *review of all processing records for completeness and accuracy and verification that the tissue was processed in accordance with the SOPM and meets defined technical specifications;*
  - 4) *review of tissue obtained and specimens produced from each collection for verification that the disposition of each tissue specimen is traceable;*
  - 5) *verification of resolution of all error or accident reports (if any) potentially related to the safety or quality of the tissue;*
  - 6) *verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., ejaculate volume, sperm motility, concentration, morphology, and post-thaw motility);*
  - 7) *if reproductive tissue was collected by another entity, verification of the time of receipt at the reproductive tissue bank and condition of the sample upon receipt; and*
  - 8) *verification that the Medical Director has made a decision regarding donor suitability eligibility and that all directives of the Medical Director regarding the donor were implemented.*

### **F1.310 Review of On-Site Processing Records**

If processing was performed on site, there shall also be written documentation that all quality ~~Quality Assurance and Control~~ measures were performed and acceptable according to the written SOPM. This includes but is not limited to:

- 1) *review of all processing and packaging bacteriologic testing results for completeness and acceptability;*
- 2) *review of all test or environmental testing results generated for completeness and acceptability;*
- 3) *review of all lot numbers and expiration dates recorded (e.g., materials such as recovery kits, culture media, processing solutions) for verification that all were within acceptable ranges; and*
- 4) *review of all processing records for: completeness and accuracy; ~~for~~ verification that tissue was processed in accordance with the SOPM; and ~~meets~~*

[conformance to](#) defined technical specifications.

## F2.000 OTHER RELEASE

### F2.100 Tissue Release Based on Tissue Utility

Pre-established release criteria based on *tissue* utility *must* be developed. If *tissue* other than *reproductive tissue* is *distributed* or dispensed for *transplantation*, there *shall* be in each instance, documentation of:

- 1) ~~*donor suitability*~~ [eligibility](#) and *tissue processing* information available at the time of release. All ~~*donor suitability*~~ [eligibility](#) requirements in F1.100 ~~Donor Suitability Review~~ *must* be met with the exception of a review of the autopsy report (if applicable) and pending culture results;
- 2) Medical Director or licensed physician designee review of all relevant information present;
- 3) [approval](#) of the release by the Medical Director or licensed physician designee;
- 4) [a](#) written statement issued to the *end-user* physician indicating what information required by the *SOPM* and/or these *Standards* is available and what information is not available for review, and when it is expected that the information will be available; and
- 5) [a](#) statement from the *end-user* physician indicating his/her understanding that the *tissue* is being released using available information.

Relevant final results *shall* be forwarded promptly to the *end-user* physician upon completion of testing. Documentation of the release based on *tissue* utility *shall* be maintained in the *donor record*. These *records shall* be maintained together or summarized in a log.

### F2.200 Special Circumstances in Release of Reproductive Tissues

(R) Release of *reproductive tissue* may be considered in the special cases of:

- 1) [reproductive tissues](#) from *client depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, HBsAg, or any other test, excluding CMV, without subsequent negative confirmative testing as approved by the Medical Director; or
- 2) [reproductive tissues](#) from *client depositors* that have not been tested or do not meet current *Standards*; or
- 3) [directed donors](#) who have completed all required testing and screening according to *Standard* [but](#); ~~who~~
  - a) had reactive test results ~~on either initial or repeat tests~~; or
  - b) are determined ineligible according to screening criteria; ~~or~~
- 4) ~~*Directed donors who have not completed the 180-day quarantine and re-testing requirement.*~~

In the case of release for one of the ~~four~~ [three](#) circumstances listed above, the following documentation is required (refer to G3.210 ~~Summary of Records Content~~, and G3.220 ~~Package Insert Content~~, for *labeling* requirements):

- 1) [a](#) written statement *signed by a responsible person at the reproductive tissue bank* disclosing the *deviation(s)* from *Standards* and description of potential risks to the *recipient*; and
- 2) [acknowledgement](#) from the medical provider indicating he/she:
  - a) has received the written statement from the *reproductive tissue bank* and acknowledges the *deviation(s)* from *Standards*;
  - b) has had ample opportunity to discuss the implication(s) with a *responsible person* at the *reproductive tissue bank* and other medical authorities;
  - c) agrees to fully explain the implication(s) to the *recipient* and provide her ample opportunity to ask questions and consult with experts of her choice; and
  - d) will document *informed consent* from the *recipient*.

### **F2.300 Shipping Reproductive Tissue in Quarantine**

If *donor reproductive tissue* is to be released before completion of the *donor ~~suitability~~ eligibility* assessment, the *tissue* must be kept in *quarantine* during shipment. The labeling must include a statement that the *donor ~~suitability~~ eligibility* assessment, has not yet been completed. It *must* also include a statement indicating the *reproductive tissue* must not be *transplanted* or *transferred* until the *donor ~~suitability~~ eligibility* assessment, is complete.

## **F3.000 TISSUE FAILING REVIEW PROCESS—~~GENERAL REQUIREMENTS~~**

*Tissue* failing any portion of the review process *shall* be maintained in *quarantine* pending *resolution* or disposal and *shall* not be released for *transplantation*. Unexplained discrepancies or *deviations* from specifications *shall* be fully investigated and documented.

### **F3.100 ~~Unsuitable~~ [Ineligible](#) Donors**

If a *donor* is deemed ~~unsuitable~~ [ineligible](#) as a result of *donor ~~Suitability~~ eligibility* assessment or disease screening procedures, the finding *shall* be specifically stated in the *donor record* and in the release/*disposition* decision statement, and this determination *must* be described and communicated in writing in a timely manner to the *tissue bank* that *recovered tissue*. If the *tissue* is to be made available for nonclinical purposes from a *donor* who has been determined to be ineligible based on the results of required testing and/or screening, it *must* be *labeled*: (1)

“For Nonclinical Use Only” and (2) with the biohazard legend.

(SB) Permanent and temporary deferrals of living *surgical bone donors* and the reason(s) for such deferral *shall* be documented in the *donor record*.

### **F3.200 Technical or Quality Assurance Assessments**

If *tissue* is deemed unsuitable for release for *transplantation* for reasons other than *donor ~~suitability~~ eligibility*, the *processing* and release/*disposition* decision records *shall* specifically describe the reason(s) for the ~~unsuitability~~ determination. If this *tissue* is to be made available for nonclinical purposes it *must* be *labeled* “For Nonclinical Use Only.”

## **F4.000 TISSUE ~~RELEASE~~ [TRANSFER](#)—GENERAL**

### **F4.100 Release [Transfer](#) to Distribution Inventory**

Before *tissue* is released [transferred](#) to *distribution* inventory, appropriate release documentation *shall* be *verified*. ~~Tissue to be transferred shall be identified, inspected for integrity of packaging, and tissue and label accuracy. Final labeling, if applied at this time, shall be performed in accordance with the SOPM and Standards. Tissue for transplantation~~ may then be placed in *distribution* inventory. ~~These checks, the transfer~~ [The identification of the \*tissue\* transferred](#), date of transfer, and staff performing the transfer and verifications [and transfer](#) *shall* be documented.

#### **F4.200 Transfer to Other Inventory Locations**

*Disposition* of *tissue* that is transferred *shall* be documented (e.g., discard, research, further processing). Date of transfer, staff involved, and *verification* of *tissue* identity *shall* also be documented.

## SECTION G LABELING

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### G1.000 LABELS AND LABELING

#### G1.100 Nomenclature

Nomenclature used to describe *tissue*, cultures, blood specimens and other *donor* specimens (e.g., lesions, lymph nodes) *shall* be specified in the *SOPM* and be applied consistently. For *finished tissue*, units of measurement and the *processing* that *tissue* has received *shall* also be specified in the *SOPM*.

#### G1.200 Label List

A list of *labels* used *shall* be maintained, as well as an example of every *label* that is utilized by the *tissue bank*. Dates of use (start and discontinuance) *shall* be *recorded*. Changes pertaining to *labels* and communicating changes *shall* be expected from *tissue banks* that supply *labels* to other *tissue banks* and *tissue distribution intermediaries*.

#### G1.300 Labeling Integrity

*Labels* *shall* be designed and *qualified* to be legible, indelible, and affixed firmly to the *container* under anticipated *storage* conditions for length of use. See K1.200. *Labels* applied by *tissue bank* staff *shall* not be removed, altered, or obscured except to correct *labeling errors*. When applicable, this also applies to *labeling materials*. Suppliers of *labels* deemed *critical* are responsible for *establishing* specifications.

#### G1.400 Claims

All *labeling claims* *shall* be clear, accurate, substantiated, and not misleading.

### G2.000 LABELING PROCESS

#### G2.100 General Requirements

There *shall* be *SOPs* ~~designed~~ established and followed to ensure that ~~correct~~ approved *labels*, *labeling*, and *packaging materials* are used for *tissue*. ~~Each *Tissue* labeling phase for all *tissue* shall be documented at each step (e.g., *unprocessed*, *in-processed*, *quarantined*, and *rejected*, released for *Distribution*) shall be documented.~~

#### G2.200 Relabeling

If *tissue* is to be *reabeled* for any reason, such as *label* detachment or to correct a *labeling error*, the *tissue bank* *shall* establish a *relabeling procedure* delineating the methods to be utilized, conditions under which *tissue* may be *reabeled*, and the staff authorized to perform such activities. The reasons for, and events surrounding, the *relabeling* of *tissue* *shall* be documented in the *records*. *Relabeling* methods *shall* consider *storage* conditions and *label* integrity (see G1.300).

#### G2.300 Controls—General

~~There shall be appropriate~~ Labeling control procedures shall be established ~~based upon the system and equipment used in labeling operations. SOPMs shall incorporate controls including the review of labels to ensure~~ Label integrity, legibility and accuracy, and the ~~establishment of checks to prevent transcription and other labeling errors.~~ Electronic labeling systems ~~shall possess adequate controls to prevent the erroneous labeling of tissue. There shall be documentation~~ Labeling reviews and checks shall be documented and shall be included in the *records*. If a sampling plan is used, it must follow a statistically valid method, such as ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes. ~~to verify label accuracy and that labeling checks were performed.~~ The *labeling* area ~~shall be inspected prior to the start of labeling activities to ensure that all labels and packaging materials from previous labeling have been removed.~~ The inspection of the area shall be documented and included in the records.

#### **G2.310 Label Inspection**

*Labels shall meet appropriate* ~~written specifications and be approved by quality assurance staff prior to release for use by a designated person. Labels not meeting such specifications shall be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection shall be documented.~~

#### **G2.320 Label Storage**

The storage area for *labels* and *labeling materials* shall be clearly identified. Access *should* be restricted to authorized personnel only. This is not applicable to *labels* included in *tissue recovery* packs.

#### **G2.330 Labeling Process Controls—Obsolete Labels**

*Procedures shall be established to retrieve obsolete and/or outdated labels and labeling materials from all labeling areas and inventory locations. As each type of label is removed from inventory, one label shall be retained for the archives and the surplus labels shall be discarded. The Master Label List-label list and the SOPM shall be updated accordingly.*

#### **G2.340 Tissue and Container Visual Inspection**

Prior to *labeling* a unit of *processed tissue*, the *container* shall be inspected for evidence of impurities, defects, broken seals, or contamination that could compromise the *quality, integrity, or safety* of the *tissue*. A sufficient area of the *container* shall remain uncovered to permit inspection of the contents whenever possible. Any *tissue* or *container* suspected ~~to be of questionable quality~~ not meeting specifications shall be *quarantined* immediately pending further investigation and *resolution* following *established procedures* in the *SOPM*. This review *shall* be documented.

### **G3.000 LABELING INFORMATION**

#### **G3.100 Container Labels**

##### **G3.110 Design**

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



### G3.120 Content

Except for autologous tissue and reproductive tissue, container labels shall include: the Tissue Identification Number.

The following information shall be included on the container label unless space limitations require use of a corresponding insert:

1) the tissue identification number;

~~4~~2) descriptive name of the tissue and other information necessary for selection or use (e.g., size, right/left, medial/lateral, anterior/posterior);

~~2) name(s) and address(es) of tissue bank(s) responsible for determining donor suitability, processing and distribution. Should more than two banks be involved, the name of all banks are required but the address is only required for the bank determining donor suitability;~~

3) expiration date (if applicable), including the month, day, and year or, if only the month and year are used, the expiration date must be clearly described in labeling as occurring at the beginning or the end of the month;

4) ~~Acceptable~~ storage conditions, including recommended *storage* temperature and/or ~~acceptable~~ *storage* temperature range;

~~7~~5) quantity or other characteristics of *tissue* expressed as applicable (e.g., volume, weight, dimensions, cell density, number of viable cells or a combination of these);

~~9~~6) a reference to the *package insert*.

The following information *shall* be included on the *container label* unless space limitations require use of a corresponding insert:

~~5~~1) *disinfection or sterilization procedure* utilized (if applicable);

~~6~~2) *preservative* (if utilized) and/or method of *preservation* (if applicable);

~~8~~3) potential residues of *processing* agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and

~~2~~4) name(s) and address(es) of *tissue bank(s)* responsible for determining *donor suitability* eligibility, *processing* and *distribution*. Should more than two tissue banks be involved, the name of all tissue banks are required but the address is only required for the tissue bank determining *donor suitability* eligibility.

~~9) A reference to the package insert.~~

### G3.130 Additional Labeling Requirements

(A) The following information *shall* be included on the *container label* for *autologous tissue* unless space limitations require use of a corresponding insert:

- 1) the donor classification statement “AUTOLOGOUS DONOR”;
  - 2) ~~The patient’s name and, if available, the name of the facility where the patient is being transplanted and the patient’s hospital registration number or, if unavailable, social security number, birth date, or similar definitive~~ autologous donor identifying information such as the patient’s hospital identification number, social security number, birth date, etc.;
  - 3) a label or attached tag “FOR AUTOLOGOUS USE ONLY”; and
  - 4) if infectious disease testing or *donor* screening is not complete or has not been performed, a *label* indicating “NOT EVALUATED FOR INFECTIOUS SUBSTANCES” is required; or
  - 5) if infectious disease testing was performed and any results were positive, or if *donor* screening was performed and risk factors identified, then *labeling* with a “BIOHAZARD” *label* is required.
- (R) Cryocontainers (e.g., vials, straws or ampules) *shall* be *labeled* so as to identify:
- 1) ~~donor or client depositor identification and Batch number~~ unique identifier and/or other code that can be used by the *reproductive tissue bank* to identify the date the specimen was *cryopreserved* and the stage of development at *cryopreservation*, where applicable; and
  - 2) name, initials, or other code that can be used to identify the *reproductive tissue bank* at which the specimen was *processed*.

### G3.200 Summary of Records and Package Insert

*Tissue* determined to be suitable and released for *transplantation* *shall* be accompanied by a *summary of records* and *package insert*. A *summary of records* is not required if a *donor suitability* eligibility determination is not required (i.e., *autologous tissue* and certain types of *reproductive tissue*).

### G3.210 Summary of Records Content

A *summary of records* is required when *donor suitability* eligibility assessment ~~determination~~ has been completed and *shall* include:

- 1) a statement that the *tissue* was prepared from a *donor* determined to be ~~suitable~~ eligible based on the results of screening and testing. All results of relevant communicable disease tests performed on specimens from the *donor* and used for release of *tissue* *shall* be listed. Relevant tests include those tests that are required (see D4.230 ~~Required Infectious Disease Tests~~). For example, the CMV test result used must be listed for reproductive tissue. If a test for anti-HTLV I and/or anti-HTLV II was performed it *must* be reported. ~~To clarify expectations and to offer an example, the CMV test result used must be listed for reproductive tissue;~~
- 2) the name and address of the establishment that made the *donor suitability* eligibility assessment ~~determination~~; and
- 3) a statement that the communicable disease testing was performed by a laboratory registered with *FDA* to perform *donor* testing and certified to perform such

testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply in regard to required *labeling* involving *donor* infectious disease test results.

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

### **G3.220 Package Insert Content**

The *summary of records* may be included in the *package insert*. The *package insert* shall contain the following information:

- 1) *a* statement limiting use to specific health professionals (e.g., physicians, dentists, and/ or podiatrists);
- 2) *a* statement that the *tissue* is intended for use in one patient, on a single occasion only, or as is applicable for *reproductive tissue*;
- 3) *known* contraindications (if any) to the use of the *tissue*;
- 4) *warnings* and list of known possible significant adverse reactions;
- 5) *a* statement that *adverse outcomes* potentially attributable to the *tissue* must be reported promptly to the *tissue* supplier;
- 6) *presence* of known sensitizing agents (if any);
- 7) *a* statement that indicates that the *tissue* may transmit infectious agents;
- 8) *a* statement, if applicable, that the *tissue* may not be *sterilized* or re-sterilized.
- 9) *dosage* information (if applicable);
- 10) *description* of how the *tissue* was supplied (e.g., frozen, *lyophilized*, irradiated, *demineralized or partially demineralized*, see E2.612);
- 11) *type* of antibiotics present (if applicable);
- 12) *concentration* of *preservative(s)* and/or *cryoprotectant(s)* in final package solution (if applicable);
- 13) *instructions* for opening the *package* and/or *container*;
- 14) *instructions* for preparation of *tissue* for *transplantation*;
- 15) *expiration* time of *tissue* following reconstitution (upon preparation for use);
- 16) *instructions* indicating that once a *container* seal has been compromised,

the *tissue* shall be either *transplanted*, if appropriate, or otherwise discarded;

- 17) a acceptable *storage* conditions and *tolerance limits*;
- 18) special instructions required for the particular *tissue*, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”);
- 19) a statement that it is the responsibility of the *tissue dispensing service*, *tissue distribution intermediary*, and/or *end-user* clinician to maintain *tissue* intended for *transplantation* in appropriate *storage* conditions prior to further *distribution* or *transplant* and that *recipient records* must be maintained for the purpose of *tracing tissue* post-transplantation;
- 20) a statement that the *tissue* is “DONATED HUMAN TISSUE,” when applicable; and
- 21) effective date or other traceable version identifier.

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

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

- 1) warning against using a graft if there is evidence that the *container* has broken or the contents have thawed;
- 2) satement that the *end-user* may not subject the *tissue* to *sterilization* (e.g., DO NOT STERILIZE the *allograft* by any method. Exposure of the *allograft* and the *packaging* to irradiation, steam, ethylene oxide, or other chemical sterilants will render the *allograft* unfit for use);
- 3) donor age (and blood type, if available);
- 4) date of dissection or *preservation*;
- 5) tissue warm ischemic time;
- 6) tissue cold ischemic time;
- 7) graft sizes (e.g., diameter and length);
- 8) graft physical descriptions and evaluations, including description of imperfections and evaluation criteria;
- 9) the type of *cryoprotectant* (if applicable) and clear statement regarding the possibility of residuals;
- 10) a description of the temperature-sensitive nature of the grafts; and
- 11) instructions for preparation of *tissue* for use.

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

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

- (R) See F2.200 ~~Special Circumstances in Release of Reproductive Tissues~~ for additional requirements that may be applicable in certain directed donor or client depositor situations, ~~regarding release of tissue from Directed Donors with reactive test results, incomplete 180-day quarantine, or who are ineligible based on screening, as well as Client Depositors with reactive test results or incomplete test results.~~

*Reproductive tissue* in the following categories require additional information in *package inserts* as listed below:

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

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

- a) For all *reproductive tissue*, include the statement: “For use by  
Sexually  
Intimate Partner Only.”
  - b) For all reproductive *client depositors* who were not tested or screened using all parameters required for either a *semen* or egg *donor*, including the required tests and time limits for *donor* testing, include the statements:
    - 1. “Not evaluated for Infectious Substances”; and
    - 2. “WARNING: Advise Recipient of Communicable Disease Risks.”
  - c) For all reproductive *client depositors* who have reactive or positive test results:
    - 1. biohazard symbol; and
    - 2. “WARNING: Reactive test results for (insert name of test).”
- 2) If the intended recipient is NOT the sexually intimate partner of either *gamete* provider, the following *labeling* is required in addition to a *summary of records*:
- a) *Directed donors (semen, oocyte, and/or embryo)* with reactive test results:
    - 1. biohazard symbol;
    - 2. “WARNING: Reactive test results for (insert name of test)”;

3. "WARNING: Advise Recipient of Communicable Disease Risks."

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

1. biohazard symbol; and

2. "WARNING: Advise Recipient of Communicable Disease Risks."

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

~~1. "Not evaluated for Infectious Substances"; and~~

~~2. "WARNING: Advise Recipient of Communicable Disease Risks."~~

- 3) If the intended *recipient* is NOT the sexually intimate partner of either *gamete* provider, and the *tissue* is from *anonymous* or *directed embryo donors* in cases where the *gamete* provider(s) was (were) not initially tested as *donors*, but were re-tested following ~~180-day~~ 6-month quarantine, include the statement: "Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently."

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

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

- 4) If the intended recipient is NOT the sexually intimate partner of a gamete provider who initially cryopreserved reproductive tissue as a client depositor but was subsequently screened and tested as a directed donor in cases where additional collections are unavailable, include the statement: "Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently."

45) Reproductive tissue intended for research:

- a) *Client depositor reproductive tissue* when *gamete* provider(s) were not tested or screened using all parameters required for either a *semen* or *egg donor*, including the required tests and time limits for *donor* testing, or *donor (anonymous or directed) tissue* has not completed ~~180-day~~ 6-month quarantine release requirement:

1. "For Non-Clinical Use Only"; and

2. "Not evaluated for Infectious Substances."

- b) *Anonymous donor* (anonymous or directed) tissue that has completed ~~180-day~~ 6-month quarantine release requirement:

1. “For Non-Clinical Use Only.”
- c) *Client depositor* or *donor (anonymous or directed) tissue* from *gamete* provider(s) who had reactive test results OR have been determined to be ineligible:
  1. biohazard label;
  2. “For Non-Clinical Use Only”; and
  3. if applicable, “WARNING: Reactive test results for (insert name of test).”

### **G3.300 Transport Package Label Content**

#### **G3.310 Domestic Shipments**

The transport *package label* shall include the following information:

- 1) name, address and telephone number of the *distribution* facility;
- 2) name and address of the destination;
- 3) prominent identification of contents as “DONATED HUMAN TISSUE.” Note: If the *reproductive tissue* in the shipment was *collected* from a *client depositor*, prominent identification as “HUMAN TISSUE”;
- 4) recommended storage conditions ~~and transport expiration date (if applicable)~~;
- 5) validated expiration date/time of the transport package when the storage temperature must be controlled;
- 56) type and quantity (when the quantity is applicable) of refrigerant or other hazardous materials enclosed-in the transport *package*; and
- 67) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).

#### **G3.320 International Shipments**

*Labels* for international shipments *shall* contain all of the information required for domestic shipments; however, information *may* be modified to meet requirements of the federal government and those of the receiving country.



## SECTION H DISTRIBUTION AND DISPENSING

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### H1.000 DISTRIBUTION AND DISPENSING—GENERAL

There *shall* be *SOPs* for the following: receipt of *tissue* orders, unit selection, final *container*, and/or *package* inspection, shipping, and transportation of *tissue* for *transplantation*.

#### H1.010 Solutions

~~(S, CT)~~

~~Any specifically required solutions not readily available to the end-user that are needed to prepare the *tissue* for use *shall* be made available to the utilizing facility.~~

~~(V) — Any specially required solutions (not readily available in an operating room) needed to complete the vascular *Allograft* operative preparation procedure shall be made available to the utilizing facility. Each tissue bank should have procedures detailing proper storage, handling, and return of any required solutions.~~

#### H1.100 Tissue Distribution and Dispensing Restrictions

Provision of *tissue* for *transplantation* *shall* be restricted to hospitals, free-standing medical facilities, *tissue banks*, *tissue dispensing services*, and *end-users* (e.g., physicians, dentists, podiatrists or other medical professionals) for use in *recipients* with the veterinary use exception that follows. Human *tissue* for *transplantation* *shall* not be offered, *distributed* or dispensed for *veterinary use* unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. If *tissue* is provided to a *tissue distribution intermediary*, the *tissue distribution intermediary* *shall* meet the requirements of Section M of these *Standards*. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or in a record of informed consent. Distribution restrictions must be communicated to distributors. Periodic verification of activities performed by the tissue distribution intermediary shall be documented (e.g., a paper audit, on-site audit, on-site inspections, etc.). See B1.520.

#### H1.110 Client Depositor Authorization

~~(R)~~ ~~Cryobanked~~ Reproductive tissue *shall* be released for use by the *client depositor* or the *client depositor's* sexually intimate partner only. Prior to release of the specimens, a statement containing a *verified signature* from the *client depositor* *shall* be obtained indicating the relationship between the intended *recipient* and the *client depositor*.

~~Cryobanked~~ Reproductive tissue for potential therapeutic insemination, use in another *assisted reproductive technology procedure*, or for other specified *disposition* *shall* be released ~~only upon~~ as per written authorization of the *client depositor*, if of legal age or, if not, by that of parent, legal guardian, or his/her

legally appointed designee.

#### **H1.120 Reproductive Tissue Distribution Restrictions**

- (R) A *client depositor* who requests that his/her ~~eryobanked~~ *reproductive tissue* be *distributed* to a *recipient*, who is not the *client depositor* or who is not the sexually intimate partner of the *client depositor*, shall be treated as a *directed donor(s)*. All *directed donor(s)* must be fully tested and screened in a manner consistent with *donor* protocols and these *Standards*. If additional *collections of reproductive tissue* are unavailable due to the infertility or health condition of the now *directed donor*, appropriate measures should be taken to screen and test the *directed donor* prior to distribution (excluding testing for *Neisseria gonorrhea* and *Chlamydia trachomatis*). Alternatively, the *client depositor* *reproductive tissue* may be *distributed* in *quarantine* with proper *labeling* to clearly identify the *donor* ~~suitability~~ *eligibility* assessment is not yet complete. See F2.300.

*Reproductive tissue* shall not be *distributed* to private individuals unless the request is in the form of a physician's written order for such *distribution*.

#### **H1.130 Donor Conceived Offspring Limitations**

- (R) A written policy addressing limitation of the number of offspring by a *gamete donor* shall be *established*. The policy shall include the upper limits deemed acceptable to the *reproductive tissue bank* and shall describe the methods that will be used to comply.

#### **H1.200 ~~Transfer of~~ Distributing Tissue to Other Tissue Banks/Dispensing Services**

When a *tissue bank* ~~forwards~~ *distributes* *tissue* obtained from another *tissue bank* or *tissue distribution intermediary*, all accompanying original *labeling materials* or other enclosures shall be ~~forwarded~~ *distributed* with the *tissue*.

#### **H1.210 Consignment Inventory Management**

If *tissue* is provided on *consignment*, the *distributing tissue bank* shall maintain procedures to ensure *traceability* and that appropriate *storage conditions* are maintained during *consignment*, transfer or return.

#### **H1.300 Requests for Donor Status and Tissue Processing Information**

*Donor risk assessment*, *tissue-related information*, and *tissue processing details* shall be made available to the *end-user* upon request, except such information that may infringe upon the confidentiality of *donor* information.

#### **H1.400 Distribution Records**

~~*Distribution*~~ *Records* shall be maintained by the *tissue bank* that ~~ships~~ *distributes* *tissue* (including unfinished or as yet unreleased *tissue*) to other entities. These *records* shall be designed to permit *tissue* to be *traced* from the *donor* to a *consignee* or *end-user*, and from a *consignee* or *end-user* back to the *donor*. *Tissue distribution records* shall include:

- 1) date of order placement;
- 2) name and address of *consignee*;

- 3) name of individual placing the order;
- 4) type and quantity of *tissue* ordered;
- 5) information pertaining to *tissue* shipped including:
  - a) identification number(s) of *tissue*(s);
  - b) collection and/or expiration date of *tissue*;
  - c) date of shipment;
  - d) ~~Type and amount of refrigerant, if any, used for shipment;~~ type of refrigerant, and quantity of refrigerant when applicable, in the shipment;
  - e) mode of transportation and/or courier; and
  - f) name of the staff member filling the order.
- 6) identifying information, if available, about the intended *recipient*.

#### **H1.410 Responsibility**

The *tissue bank* shall establish *recipient* follow-up data collection protocols, and procedures to evaluate information received.

### **H2.000 TISSUE FOR RESEARCH—~~GENERAL POLICIES AND PROCEDURES~~**

Facilities providing *tissue* for research and other non-transplantation purposes *shall* develop detailed relevant specific policies and *procedures*. *Informed consent* or *authorization* for research and/or education *shall* be obtained. See the series of standards at D2.000 and D3.000.

#### **H2.100 Written Requests**

All requests for human *tissue* intended for research use *shall* be submitted in writing. The request *shall* indicate the type of *tissue* requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the *tissue*.

#### **H2.200 Review and Approval**

*Tissue* requests for research purposes *shall* be reviewed and approved based on legal, ethical, and technical considerations defined in the *SOPM*.

### **H3.000 PACKAGING AND SHIPPING**

#### **H3.100 Solutions**

Any specifically required solutions not readily available to the end-user that are needed to prepare the *tissue* for use *shall* be made available to the utilizing facility.

#### **~~H3.100~~ H3.200 Integrity**

*Packaging shall be designed to ensure ~~tissue integrity~~ quality and prevent contamination of the contents of the final *container(s)*.*

### **H3.200 H3.300 Tissue Storage Environment**

Maintenance of defined environmental conditions during transit *shall* be required. Specific environmental conditions *shall* be in accordance with the *SOPM*, these *Standards* and applicable laws and regulations.

### **H3.300 H3.400 Validation and Expiration of Transport Package Container**

If *tissue* to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport ~~container~~ package to maintain the required environmental conditions *shall* be demonstrated and documented in a *validation* study. The length of time that these conditions can be maintained by the transport ~~container~~ package *shall* also be determined and documented. Expiration dates (and time if applicable) of the transport ~~container~~ package *shall* be noted on the outside of the transport ~~container~~ package.

### **H3.400 H3.500 Quality Control of Reusable Shipping Packages**

If *tissue* to be shipped requires specific environmental conditions other than ambient temperature, and the transport package can be reused, *QC* monitoring of ~~shipping the~~ transport *packaging must* be performed according to the *SOPM* to verify package integrity has been maintained. ~~maintenance of the required environmental conditions~~. These *QC* checks *shall* be documented.

### **~~H3.410 Residual Levels in Packaging~~**

~~(C, V) If ethylene oxide is used to Sterilize processing or packaging components that come in contact with the *Allografts* (e.g., *Disinfection* jars or packaging pouches), residues of ethylene oxide, ethylene glycol, and ethylene chlorohydrin should be evaluated. Refer to ISO 10993-7.~~

### **H3.500 H3.600 Final Pre-shipping Inspection**

Prior to shipping, ~~All packages shall be subjected to a final inspection~~ inspected to ensure that the ~~Containers~~ external packaging and labels are ~~intact~~ undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. ~~Labels are accurate, the Package Insert is present, and that the final package is appropriate for the type and requirements of the tissue being shipped.~~ The exterior of the transport ~~container~~ package *shall* be inspected to *verify* that requirements in ~~Standard G3.310~~ are met. These inspections *shall* be documented, including identification of staff conducting inspections.

### **~~H3.600~~ H3.700 Transportation**

The mode of transportation selected *shall* be determined by any special shipping and handling requirements of the *tissue* and/or shipping refrigerants, by shipping restrictions of commercial carriers, and the urgency of the *tissue* request.

## **H4.000 RETURN OF TISSUE**

A *tissue bank* *shall* establish a policy authorizing or prohibiting the return of *tissue* in its original, unopened *container*. If returns are permitted, the integrity of the *container*, *package*, and *labeling* *shall*

be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required *storage* temperatures, *tissue* shall not be returned to *distribution* inventory. Information pertaining to the return of *tissue* shall be recorded in the *disposition records* for that shipment of *tissue* as follows:

- 1) documentation of *package* and/or *container* examination;
- 2) documentation of *end-user* handling, *storage*, and shipping conditions;
- 3) reason for the return;
- 4) disposition of the returned *tissue*(s); and
- 5) date and name of the staff member authorized to evaluate and determine the *disposition* of the *tissue*(s).

~~(R) — Cryopreserved donor reproductive tissue that has been released to a physician or designee and subsequently not used and returned to the Reproductive Tissue Bank in the frozen state shall not be redistributed for use by any other physician or designee.~~

#### **H4.100 Temperature Records**

For *tissue* that requires controlled environmental temperatures, at a minimum, documentation is required that attests the *tissue* was maintained at required *storage* temperatures.

~~(S) — Refrigerated skin may be returned to inventory if it has been maintained above freezing (0°C) to 10°C in a closed Container.~~

~~Frozen/cryopreserved skin that has been thawed shall not be returned to the skin bank inventory. Frozen/cryopreserved skin shall not be assigned for use to another patient if the package has been opened.~~

#### **H5.000 FIELD CORRECTIONS AND REMOVALS —GENERAL**

*Tissue banks* shall have specific written policies and *procedures* for the initiation and performance of a field correction or removal, if applicable. *Procedures* shall include, but are not limited to, the following:

- 1) evaluation and determination by a *responsible person*(s);
- 2) timely identification and management of affected inventory;
- 3) assessment of associated health risk;
- 4) field communications (e.g., *field notification*);
- 5) types of *field corrections* or *removals* (e.g., *recall*, *market withdrawal*) and *stock recovery*;
- 6) reporting requirements;
- 7) evaluation of effectiveness;
- 8) termination or closure;

- 9) documentation and *record* requirements; and
- 10) review by *management with executive responsibility*.

*Tissue banks* not directly responsible for conducting *field corrections* or *removals*, but that perform activities that could lead to the need for a *field correction* or *removal* (e.g., *tissue recovery*, *donor screening*, *donor testing*) *shall* have policies and *procedures* for the timely notification of all affected parties regarding information related to *tissue safety* or regulatory requirements.

#### **H5.100 Circumstances That May Require Field Correction or Removal**

The need to perform a *field correction* or *removal* may be identified as a result of a *complaint*, *adverse outcome*, *accident*, *error*, *deviation*, *audit*, or by any other means. An evaluation to determine if *field correction* or *removal* is warranted *should* be made whenever *distributed tissue* may not meet specifications related to *safety*, *quality*, *traceability*, identification, function and/or use. This evaluation *must* consider both risk to health posed by the *tissue* and applicable regulatory requirements, and be documented.

#### **H5.200 Notification Responsibilities**

Upon discovery of the need for *field correction* or *removal*, the *tissue bank* *shall* promptly notify all entities to which affected *tissue* was *distributed* or dispensed as well as the *tissue bank* that *recovered* the *tissue*, if applicable.

#### **H5.300 Handling of Tissue**

All *tissues* not already *transplanted*, which are subject to *field* *correction* or *removal*, *shall* be located and *quarantined* pending *resolution* of the issue.

#### **H5.400 Reporting Requirements**

*Tissue banks* *shall* comply with all *field* *correction* and *removal* reporting requirements for applicable federal, state and international government/competent authorities under which they operate or *distribute tissue*.

For additional information, refer to FDA Guidance for Industry: Product Recalls, Including Removals and Corrections at:  
<http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm>

#### **H5.500 Field Correction and Removal Records**

All information relating to the *field* *correction* or *removal* of *tissue* and resulting communications *shall* be documented and retained on file at least 10 years beyond the date of *distribution*, the date of *transplantation* (if known), *disposition*, or expiration of the *tissue*, whichever is latest. The file *shall* include the following information:

- 1) events precipitating the *field* *correction* or *removal*;
- 2) identification and location of affected *tissue*, including *quarantine* steps;
- 3) associated risk assessment;
- 4) type of *field* *correction* or *removal* (e.g., *recall*, *market withdrawal*) and *stock recovery*;

- 5) steps taken to correct or retrieve *tissue*;
- 6) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of *field notifications* or letters and a list of those to whom notice was sent);
- 7) final *disposition* of the *tissue*;
- 8) copies of reports to regulatory authorities, accreditation organizations and certification bodies, if required;
- 9) corrective *actions* recommended and implemented; and
- 10) documentation of review; if of a medical nature, review by the Medical Director or licensed physician designee.



## SECTION J GENERAL OPERATIONS

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Each *tissue bank* shall develop written detailed policies and *procedures* in a standardized format, which shall be collected into a *standard operating procedures manual (SOPM)*. These shall be available at all locations for which they are designated, used, or otherwise necessary, and shall be utilized to ensure that all *tissue* released for *transplantation* is in compliance with ~~to~~ these *Standards* and applicable laws or regulations.

#### J1.100 Identification and Control

Policies and *procedures* shall be established for a document control system ~~identification and control of~~ for *procedures* and forms including requirements for:

- 1) approval for adequacy prior to use for intent and compliance to relevant regulatory requirements and standards;
- 2) ~~the review,~~ reviewing revisions and re-approval as needed;
- 3) identification of the current revision status and of changes to previous revisions;
- 4) distribution to points of use (i.e., all locations where access to *procedures* is needed);
- 5) legibility and ease of identification; and
- 6) prevention of the unintended use of obsolete documents and suitable identification controls for archived documents ~~if obsolete documents are retained for any reason.~~

#### J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to policies and procedures for:

- 1) ~~Donor policies and procedures, including informed consent or authorization, donor suitability~~ eligibility criteria, donor screening methods, time limits for *tissue recovery*, notification of confirmed positive test results, information sharing, construction of records, and, if applicable, reconstruction and final disposition of a deceased donor's body (series of standards at C2.000, D2.000, D3.000, D4.000 and D5.000);
- 2) ~~tissue collection, recovery,~~ acquisition and handling ~~policies and procedures, including supplies and methods used in all aspects of the operation involving the~~ recovery site ~~assessment of the Recovery Site, recovery,~~ materials management/supplies management, processing, packaging, quarantine, labeling, storage, donor ~~suitability~~ eligibility review, and/or release of *tissue* (series of standards at D5.000, D6.000 and Sections E, F and G);
- 3) ~~laboratory policies and procedures for~~ tests performed in-house, including establishment

of appropriate specifications, standards, and test *procedures* to assure that *tissue* is safe and *quality is addressed*; and for contracted laboratory testing, ~~policies and procedures~~ defining which tests *shall* be performed and how test results *shall* be received, reviewed, interpreted, and managed (~~D4.350~~ [B1.600, series of standards at D4.200, series of standards at F1.100, F1.200, F1.300 and F2.000, series of standards at K1.300, series of standards at K2.000](#));

- 4) ~~Policies and procedures for~~ purchasing controls, order receipt, ~~unit~~ [finished tissue](#) selection, final [container](#) inspection ~~of Container~~, and ~~package~~ [packaging](#) and shipping of *tissue*, as well as criteria for returning and reissuing *tissue* ([K1.300, series of standards at M3.000, M4.000, M5.000 and Section H](#));

[5\) external audits for services, suppliers, contractors, and consultants, when indicated \(series of standards at K6.000, and K1.300 and B1.521\);](#)

- ~~56)~~ [record management policies and procedures designed to maintain traceability, retain records, and facilitate \(if necessary\) product-](#) [field corrections and removals, Recall](#) and recipient notification by documentation of each step of *tissue* production from the point of *collection, recovery* and identification to final *distribution* of the *tissue* (~~E1.400,~~ [series of standards at C1.000, H5.000, L4.000, M6.000 and M7.000](#));

- ~~67)~~ [quality assurance and quality control policies and procedures for](#) of supplies, equipment, instruments, reagents, *labels*, and processes employed in *tissue collection, recovery, acquisition, processing, packaging, labeling, storage, distribution*, and preparation of *tissue* for *transplantation*, including policies ~~and/or~~ procedures [for](#):

- a) ~~for~~ labeling of cultures, blood specimens and other *donor* specimens (e.g., lesions, lymph nodes) (~~D4.350,~~ [series of standards at D5.000, and Section G](#));
- b) ~~for~~ monitoring *storage* temperatures, for defining *tolerance limits*, and for describing what, when, and how *corrective actions* are to be taken for implementing emergency transfers and determining alternative *storage* and monitoring methods for *tissue* and reagents (~~F4.200,~~ [series of standards at E4.000 and M2.000](#));
- c) ~~the investigation, documentation,~~ [investigating, documenting](#) and reporting of *accidents, errors, complaints, and adverse outcomes* ([series of standards at K4.000](#));
- d) ~~for the performance of~~ [performing field corrections, and removals, and stock recoveries,](#) if applicable, and ~~for~~ the timely notification of affected parties regarding information related to *tissue* safety or regulatory requirements ([series of standards at H5.000, L6.000 and M6.000](#));
- e) ~~requiring notification of~~ [notifying management with executive responsibility of any field corrections, or removals, stock recoveries,](#) investigations, inspection reports, or regulatory actions ([series of standards at H5.000 and K4.000](#));
- f) ~~that establish which~~ supplies, reagents, materials and equipment [and identifying those that](#) are considered *critical* (~~D5.100, E1.300,~~ [E2.000, J5.100](#));
- g) [maintaining equipment management programs that include](#) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment ([series of standards at J5.000](#));
- h) describing the receipt, identification, storage, handling, sampling, testing, and

subsequent approval or rejection of *containers*, packaging materials, *labels*, reagents, and supplies ([series of standards at D5.000, E1.000, and E2.000, J5.500 and Section G](#)); and

- i) ~~for~~ monitoring *in-process controls* and managing events such as failed test runs and failure of a *lot* to meet established specifications (Section K).

~~78) Policies and procedures for assigning~~ [time limits and temperature for pre-processing quarantine storage, processing, and](#) expiration dates (~~E2.520, E4.200- E3.400, H3.400 and K1.200~~);

~~89) Policies and procedures for handling requests for research~~ *tissue* ([series of standards at D1.200, H2.000](#));

~~910) Procedures for disposal~~ [disposing](#) of medical waste and other hazardous waste ([series of standards at J3.000](#));

~~1011) covering~~ emergency and safety policies and procedures, including reporting of staff injuries and potential exposure to blood-borne pathogens ([series of standards at J3.000](#));

~~1112) Procedures assigning responsibility for~~ [maintaining](#) the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used ([series of standards at J4.000 and J5.000](#));

[13\) describing the design or arrangement of the physical plant to meet operational needs such as designation of spaces, environmental monitoring, and security \(series of standards at J4.000\);](#)

~~1214) Policies and procedures describing manual methods for tissue banking activities in the event of electronic or equipment malfunction~~ ([series of standards at K6.000 K7.000](#));

~~1315) Policies and procedures describing requirements of training programs~~ [requirements](#) for technical and *QA* staff ([series of standards at J2.000](#)); and

~~1416) Policies and procedures for identification~~ [identifying](#) and control of [controlling](#) procedures and forms including requirements (J1.100, J1.400).

### **J1.300 Implementation**

The *SOPM* and associated *process validation* studies *shall* be reviewed and approved by appropriate individuals as dictated by content. All [policies and procedures of a medical nature](#) ~~medically-related portions of the *SOPM*~~ *shall* be reviewed and approved by the Medical Director. Upon implementation, all portions of the *SOPM* *must* be followed as written. Minor *deviations* from the *SOPM* *may* be authorized in writing by the Medical Director, or *QA* designee provided the *deviation* is in compliance with these *Standards*.

### **J1.400 Modifications**

The *SOPM* *shall* be updated to reflect modifications or changes, and *shall* include a description of the change, justification for the change, identification of the affected documents, the *signature* of the approving individual(s), the approval date, and when the change becomes

effective.

Prior to implementation, each modification shall be approved by appropriate individuals or the Medical Director, as dictated by content, and training *shall* be provided to pertinent staff. Implementation dates *shall* be recorded for all affected *procedures*. Obsolete documents *shall* be promptly removed from all points of use or otherwise prevented from unintended use.

### **J1.500 References**

Copies of publications cited in support of policies or procedures *shall* be maintained at the *tissue bank*.

### **J1.600 Annual Review**

An annual review of ~~all policies and procedures~~ the SOPM, and the safety manual if separate, *shall* be performed and documented.

- 1) the Medical Director shall review relevant policies and procedures of a medical nature (e.g., donor suitability eligibility, and adverse outcomes);
- 2) management with executive responsibility, or a responsible person designee, shall review policies and procedures to ensure adequacy in regard to current practice, and applicable standards, laws or regulations; and
- 3) staff shall review policies and procedures for which they have been trained and are currently responsible.

### **J1.700 Staff Access and Review**

Current copies of the *SOPM* applicable to specific staff functions *shall* be in designated locations and available to the staff at all times. New and revised policies and *procedures* *shall* be reviewed by applicable staff prior to implementation. Documentation of ~~their~~ review and any associated training *shall* be maintained at least 16 years after termination of employment or as required by applicable laws or regulations, whichever is longer.

### **J1.800 Inspections**

The *SOPM* *shall* be made available for inspection upon request by the AATB or authorized regulatory agencies.

### **J1.900 Archives**

A file of archived *SOPs* *shall* be maintained in historical sequence for 16 years after discontinuation. The *records* *shall* indicate the inclusive dates that each policy and/or *procedure* (including forms, letters, *labels*, and other specific documents) was in use.

## **J2.000 TECHNICAL AND QUALITY ASSURANCE STAFF—TRAINING/CONTINUING EDUCATION**

### **J2.100 Training**

Training *shall* be conducted for technical and *QA* staff to maintain *competency* in *procedures* and familiarity with applicable regulations and AATB *Standards*. Training *shall* encompass the following areas, as applicable: new employee orientation; the *SOPM*; technical training;

*QA; electronic systems; and continuing education. All training activities shall be documented. Training records shall be retained for 16 years after termination of employment or as required by law, whichever is longer.*

- 1) ~~As part of their training, p~~Personnel shall be made aware of their designated functions and of the consequences of the improper performance of their designated functions. ~~specific jobs.~~
  - 2) Personnel ~~who performing verification and validation activities shall be made aware that of accidents and errors that may occur~~ during the performance of their designated functions. ~~as part of their job functions.~~
- (SB) Training shall be conducted to maintain *competency in procedures* and familiarity with appropriate regulations and AATB Standards. Training shall be conducted for all staff whether they are employees of the *tissue bank*, contracted employees, or other individuals (e.g., hospital staff) who are responsible for determining *donor suitability-eligibility*, or recovering, or packaging the tissue.

## **J2.200 Competency**

Technical staff *must* demonstrate *competency* ~~for in the particular operations for which they have received training~~ their designated functions (including a thorough understanding of relevant the policies, *procedures, process controls*, and regulatory requirements). ~~and to which they are assigned.~~

## **J2.300 Continuing Education**

Technical staff *shall* participate in continuing education, which may include training courses, technical meetings, and any other educational programs pertaining to ~~assigned~~ designated functions. Such participation *shall* be documented.

## **J2.400 Training Records**

Training *records shall* be maintained for each employee with documentation of the following:

- ~~1) Training checklist for new employees and employees with newly assigned tasks;~~
- 21) delineation of functions that each employee is authorized and trained to perform;
- 2) initial training of new employees;
- 3) initial training of newly designated functions of existing employees;
- ~~34) Documentation of review and training prior to implementation of new and/or revised sections of the SOPM;~~
- 45) annual review of policies and procedures for which the employee's has been trained designated functions, including safety *procedures* (see J1.600);
- 56) annual attendance at safety hazardous materials training; and
- 67) attendance at workshops, seminars, meetings, or other continuing education programs.

## **J3.000 SAFETY PRACTICES**

### **J3.100 Work Environment**

Each *tissue bank shall* provide and promote a safe work environment by developing, implementing, and enforcing safety *procedures*. These *procedures shall* be incorporated into the *SOPM* or reside in a specific Safety Manual which is referenced by the *SOPM*. ~~The~~ *Procedures shall* be written in accordance with applicable Occupational Safety and Health Administration (OSHA) regulations, guidelines established by the *CDC*, and applicable laws or regulations. All safety *procedures shall* be ~~approved and~~ reviewed annually.

### **J3.200 Procedures**

Safety *procedures shall* include, but are not limited to, the following:

- 1) *instructions* for contacting emergency personnel and the establishment of evacuation routes and *procedures* in the event of fire or disaster;
- 2) *procedures* for management of worker injury including possible exposure to hazardous materials or blood-borne pathogens. Such *procedures shall* require a written report of the incident, including documentation of medical care received, management notification, and actions to prevent recurrence;
- 3) *delineation* of Universal Precautions as defined by the *CDC*;
- 4) *procedures* specifying the proper storage, handling, and utilization of hazardous materials, reagents and supplies, including pertinent ~~Materials~~ Safety Data Sheets; and
- 5) *procedures* outlining the steps to be followed in cleaning bio-hazardous spills.

### **J3.300 Hazardous Materials Training**

A training program *shall* be designed to inform employees about chemical, biological, and, if applicable, radioactive hazards of the workplace as well as the use of personal protection ~~protective devices~~ equipment to reduce the risk of exposure to these hazards.

### **J3.400 Universal Precautions**

Universal Precautions, as defined by the *CDC*, *shall* be implemented and enforced to reduce the potential exposure of staff to communicable diseases.

### **J3.500 Immunization**

Hepatitis B vaccination *shall* be offered free of charge to all non-immune personnel whose job-related responsibilities involve the potential exposure to blood-borne pathogens. Personnel files *shall* include documentation of receipt of vaccination or refusal of immunization with hepatitis B vaccine.

### **J3.600 Hazardous Waste Disposal**

Biohazardous human *tissue*, medical waste, and other hazardous materials ~~utilized shall~~ be disposed of in accordance with applicable laws or regulations in such a manner as to minimize environmental impact and exposure ~~of~~ to personnel. Medical waste and hazardous material tracking *records shall* be maintained in accordance with the regulations of the regulatory agency charged with management oversight.

### **J3.700 Personnel**

#### **J3.710 Attire**

Personnel engaged in the *Recovery, Processing, Preservation*, or packaging of tissue shall be suitably attired. Attire shall include personal ~~protection devices~~ protective equipment to minimize the spread of transmissible pathogens among and between *donors, tissue*, and staff.

#### **J3.720 Infections**

Any staff member shown (either by medical examination or supervisory observation) to have a serious infectious condition (e.g., an apparent illness or open lesion) that *may* adversely affect the *safety* of the *tissue shall* be excluded from the *recovery, processing, preservation*, or packaging of *tissue* until the condition is determined to be resolved. All staff members *shall* be instructed to report, to supervisory personnel, any health conditions that *may* have an adverse affect on *tissues*.

### **J4.000 FACILITIES**

#### **J4.100 General**

The physical plant *shall* be designed or arranged to meet operational needs. The premises *shall* be maintained in a clean, sanitary, and orderly manner with adequate plumbing, drainage, lighting, ventilation, and space. Adequate, clean, and convenient hand washing facilities *shall* be available for personnel and for *donors* when applicable. Specific suitability parameters for the *recovery site* (see D5.500 ~~Recovery Environment~~), or where *collection* of anonymous *semen* donation takes place, *shall* be evaluated. Areas of the facility where *donor screening and/or obtaining authorization or informed consent* takes place *should* be arranged to prevent errors and maintain confidentiality of information discussed.

#### **J4.200 Designated Space**

To prevent *errors* and/or *cross-contamination* of tissue, the following critical procedures shall be performed in designated areas of adequate size:

- 1) *donor screening*;
- 2) *obtaining authorization or informed consent*;
- 3) *processing*;
- 2) *quarantine* storage of *in-process materials*;
- 3) *other quarantining*;
- 4) *labeling*;
- 5) *storage* of *distributable* inventory;
- 6) *quality assurance/control* functions;
- 7) *receipt* and storage of *containers, container labels*, supplies, and reagents;



- 8) storage of medical waste;
- 9) irradiation and other *sterilization procedures*; and
- 10) final product inspection and *distribution* activities.

#### **J4.210 Routine ~~Cleaning~~ Decontamination and Record Retention**

Facilities used for *collection, recovery, processing, or preservation*, or for other activities where there is potential for *cross-contamination* of *tissue* or exposure to blood-borne pathogens, *shall* be subjected to routine, scheduled, documented decontamination (sanitation) *procedures*. Cleaning events performed by *tissue bank* personnel *shall* be documented and retained for three (3) years after their creation.

#### **J4.300 Environmental Monitoring**

*Environmental monitoring procedures shall* be established, where appropriate, as part of the *QA program*. Monitoring *procedures may* include, but are not limited to, static and dynamic particulate air samplings (e.g., air bacterial content assays) equipment and personnel monitoring ~~if where product-tissue contact occurs~~, and work-surface cultures. Frequency of sampling *shall* be based on related industry guidelines, the results of prior samplings or suitable justification. ~~or related industry guidelines~~. *Procedures shall* include ~~acceptable test parameters~~ tolerance limits and *corrective actions* to be implemented in the event that ~~parameters~~ limits are exceeded. Each monitoring activity *shall* be documented and results trended.

*Environmental monitoring* at the *recovery site* is not required, however pre-established parameters designed to prevent contamination and *cross-contamination must* be met (see D5.500 ~~Recovery Environment~~).

Rooms used for storage of liquid nitrogen tanks *should* be periodically monitored for oxygen levels if not appropriately ventilated.

#### **J4.400 Security**

*Tissue banks shall* maintain adequate physical security to safeguard *tissue* inventory and *records* as well as to prevent the entry of unauthorized individuals. Such security *may* be in the form of personnel, electronic or mechanical devices or barriers, or configuration of the physical plant. Limited access areas shall be established as appropriate, permitting entry of only those personnel (including auditors and inspectors) who are authorized by supervisory personnel ~~shall enter those areas of the building or facility designated as limited access areas~~.

### **J5.000 EQUIPMENT AND INSTRUMENTS**

#### **J5.100 Selection**

Equipment and instruments *should* be of appropriate quality for their intended function and use. Equipment used in the *recovery, processing, preservation, packaging, or storing* of *tissue shall* be appropriately sized, designed, and located to facilitate use, cleaning, decontamination, and maintenance. Equipment *shall* be constructed so that surfaces contacting *tissue shall* not alter the *safety or quality* of the *tissue*. See E1.300.

## **J5.200 Operation**

Equipment *shall* be operated according to manufacturer's recommendations unless it is demonstrated that modifications to operating procedures will not adversely affect either the *quality of tissue* or personnel safety. [Use of instruments shall be appropriate for the task.](#)

## **J5.300 Qualification and Maintenance**

Equipment, ~~laboratory~~ instruments, apparatus, gauges, and recording devices *shall* be *qualified* and routinely calibrated, maintained, inspected, monitored, cleaned, ~~Sterilized, disinfected, decontaminated,~~ [sterilized \(when applicable\)](#), and repaired at appropriate intervals in accordance with the *SOPM* and [established equipment](#) schedules. Calibration procedures *shall* include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there *shall* be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on *quality*. Where appropriate, *tolerance limits* *shall* be specified. ~~Documentation of such activities shall be made and maintained in equipment files for 10 years. Such records shall include documentation of repairs, rejection, return, and/or disposal of defective equipment.~~

### **J5.310 Requalification/Recalibration**

Following repairs and system upgrades, equipment *should* be requalified ~~and/or~~ recalibrated according to procedures in the *SOPM* that have been designed to be in compliance with the manufacturer's requirements and recommendations.

## **J5.400 Decontamination/~~Sterilization~~**

Equipment [and instruments](#) *shall* be cleaned, ~~Sterilized,~~ or *decontaminated*, [and sterilized \(when applicable\)](#) at appropriate intervals in accordance with the *SOPM* to prevent malfunction, contamination, *cross-contamination*, or accidental exposure [of tissue or staff](#) to blood-borne pathogens. ~~Equipment for Sterilizing materials used in tissue Recovery, Processing, or packaging shall be designed, qualified, maintained, and utilized to ensure adequate function.~~ [Procedures shall be established to track critical instruments that are cleaned and decontaminated with any other instruments. Reusable basins or bath units used for instrument soaks/washes/rinses must be cleaned and decontaminated between uses. See recommendations in AATB Guidance Document No. 3.](#)

Instruments used to *recover* and/or *process dura mater*, vertebrae, or ocular *tissue* that are known to have come in contact with *tissue* from a *donor* suspected or confirmed to have a prion-associated disease, *must* be removed and destroyed. *Tissues* from other *donors* for which those instruments were subsequently used for *recovery* or *processing* *shall* be identified, *quarantined*, withdrawn and/or *recalled* pending further evaluation.

## **[J5.500 Sterilization](#)**

[Equipment and instruments shall be sterilized if they are intended to come into contact with tissue or if they have the potential of contaminating tissue, if not sterilized. Sterilization must be performed in a manner that is consistent with applicable industry standards.](#)

[To ensure that sterilization is successful during routine processing of equipment and instruments, it is important that the following be performed at required or recommended intervals:](#)

- 1) Regular maintenance of the *sterilization* equipment: The *sterilization* equipment manufacturer's maintenance recommendations *must* be met.
- 2) Use of routine *lot* release controls: Routine *lot* release controls *must* be performed according to the specifications, and at the intervals, outlined in the following table.
- 3) Performance of efficacy monitoring: The specifications and intervals for required efficacy monitoring are outlined in the following table. In addition to the specifications found in the table, additional efficacy monitoring *may* be necessary, such as leak testing, dynamic air removal testing (DART test), and Bowie-Dick testing, and process challenge device (PCD) testing. Guidance on efficacy monitoring *may* be found in *sterilization* equipment manuals, consulting with the *sterilization* equipment manufacturer, or can be found in applicable industry standards:
  - a) steam *sterilizers*: ANSI/AAMI ST79; or
  - b) ethylene oxide *sterilizers*: ANSI/AAMI ST41

In the event that routine *lot* release controls indicate failure of the load to achieve necessary *sterilization* conditions, the *sterilizer* load contents *must* be exposed to a subsequent successful *sterilization* cycle. Frequent *sterilization* failures are often indicative of a process problem and *should* be investigated to determine the cause of failures. Investigation *may* need to include increased efficacy monitoring.

All *sterilization* accessories, to include but not limited to biological indicators, commercially available PCDs, wrappers, pouches, and *sterilization* containers, *must* be used in a manner consistent with the accessory manufacturer's instructions for use or be *validated* appropriately for the use.

<b><u>Table of Common Sterilization Methods, Cycle Parameters, Controls &amp; Monitoring</u></b>					
<b><u>Method</u></b>  <u>(other methods may be used)</u>	<b><u>Cycle Parameters</u></b>	<b><u>Routine Release Controls (for each load)</u></b>		<b><u>Efficacy Monitoring</u></b>	
		<b><u>Required</u></b>	<b><u>Recommended</u></b>	<b><u>Required</u></b>	<b><u>Recommended</u></b>
<u>Steam</u>	<u>Use the recommended parameters (e.g. exposure times, temperatures, pressures, drying times, weight and geometric complexity of load, etc.) specified in the sterilizer manufacturer's manual, or validate other cycle parameters in accordance with industry standards.</u>	<u>Verify cycle parameters were met</u>	<u>1. Utilize internal and external chemical indicators</u>  <u>2. Utilize appropriate PCD and verify as negative prior to release of load</u>	<u>Weekly: Utilize appropriate PCD*</u>	<u>Daily: Utilize appropriate PCD</u>
<u>Ethylene Oxide (EO)</u>					
<u>Vaporized Hydrogen Peroxide (VHP)</u>					
<u>Irradiation (i.e. Gamma, x-ray, electron beam)</u>	<u>Use validated cycle per ISO 11137</u>	<u>Verify cycle parameters were met</u>	<u>N/A</u>	<u>Bioburden testing, dose audits and dose mapping per ISO 11137</u>	<u>N/A</u>
<u>Other (e.g., novel, nontraditional)</u>	<u>Follow manufacturer's instructions for method selected. <i>Validation</i> is expected if manufacturer's instructions are not followed.</u>				

\* Weekly use of a PCD is not required if a PCD is already being used in each load as recommended for "Routine Release Controls".

#### **J5.500 J5.600 Storage Equipment**

Equipment used for *storage* of *tissue* shall be identified to facilitate monitoring of temperature and location of *in-process*, *quarantine*, and *distribution* inventory. Equipment

*shall be labeled* with the general nature of the contents.

*Storage* equipment used for *storing tissue*, reagents, media, refrigerants, or other laboratory solutions *shall* not be utilized for the storage of food and/or liquids for human consumption and *shall* be marked accordingly.

#### **J5.700 Record Retention**

Documentation of equipment and instrument cleaning, decontamination, sterilization, qualification, calibration, and maintenance shall be maintained in records for 10 years after their creation. Such records shall also include documentation of repairs, rejection, return, and/or disposal of defective equipment.

## SECTION K QUALITY ASSURANCE

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a *QA program*.

#### K1.100 Basic Elements

The QA programs shall include, at a minimum:

- 1) ~~Designation~~ designating and ~~management of~~ managing *quality control* functions, including:
  - a) environmental monitoring at designated intervals;
  - b) ~~Performance and documentation in maintenance records or logs of~~ performing periodic equipment and facility inspections and documenting in maintenance records or logs;
  - c) ~~Review~~ reviewing of equipment monitoring *records* for maintenance within specified *tolerance limits*, and reviewing *records* of other equipment or *processing* functions that have specified *tolerance limits*;
  - d) ~~Inspection~~ inspecting and monitoring *in-process control* results, including collection and testing of representative samples;
  - e) performing qualification of reagents, supplies, materials, instruments, or equipment when deemed *critical* or applicable; and
  - f) monitoring laboratory performance, if applicable.
- 2) performing process validation studies ~~are performed where~~ when the results of a process cannot be fully *verified* by subsequent inspection and test. Each *tissue bank* shall establish and maintain *procedures* for monitoring and ~~control of~~ controlling process parameters for *validated* processes to ensure that the specified requirements continue to be met. Each *tissue bank* shall ensure that *validated* processes are performed by qualified individual(s). For *validated* processes, each tissue bank shall document the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process ~~or~~ and the major equipment used. ~~shall be documented.~~ When changes or process deviations occur, the *tissue bank* shall review and evaluate the process and perform *revalidation* where appropriate, and shall document these activities. ~~These activities shall be documented;~~
- 3) performing equipment qualification studies ~~are performed~~ as necessary;
- 4) establishing purchasing controls ~~are established~~;
- 5) establishing procedures ~~are established~~ for implementing *corrective action* and *preventive action* ~~is taken~~ and taking action when appropriate. The *procedures* shall include

requirements for:

- a) analyzing processes, work operations, concessions, *quality audit reports, quality records, errors, accidents, complaints*, returns, and other sources of *quality* data to identify existing and potential causes of *nonconforming tissue*, or other *quality* problems. Appropriate statistical methodology *shall* be employed where necessary to detect recurring *quality* problems;
  - b) investigating the cause of *nonconformities* relating to *tissue*, processes, and the *quality system*;
  - c) identifying the action(s) needed to correct and prevent recurrence of *quality* problems;
  - d) verifying or *validating* the *corrective action* and *preventive action* to ensure that such action is effective and does not adversely affect the *finished tissue*;
  - e) implementing and *recording* changes in methods and *procedures* needed to correct and prevent identified *quality* problems;
  - f) ensuring that information related to *quality* problems is disseminated to those directly responsible for assuring the *quality* of *finished tissue* or the prevention of such problems; and
  - g) submitting relevant information on identified *quality* problems, as well as *corrective action* and *preventive actions*, for management review;
- 6) ~~Review~~ reviewing, as applicable at each *tissue bank* involved, *donor screening, informed consent or authorization, recovery, acquisition, or collection, and processing records*; and
- 7) ~~approval of~~ approving, as applicable, all *processing records and donor screening, Informed Consent or Authorization, Recovery or Collection, and Processing records* relevant medical records prior to release of *tissue* for *transplantation*;
- 78) ~~auditing~~ Performance of audit procedures;
- 89) ~~Documentation of~~ documenting formal conclusions of all *accident, error, complaint, adverse outcome*, and *field correction, or removal, or stock recovery* incidents;
- 910) ~~Maintenance of~~ maintaining documentation including, but not limited to:
- a) master copy of current *SOPs*;
  - b) ~~For those authorized to perform or review tasks, records of names, signatures, initials or identification codes and inclusive dates of employment~~ for those authorized to perform or review tasks (e.g., onsite or at a central location) ~~shall be maintained (e.g., by Human Resources, Quality Assurance, or by department)~~ ;
  - c) reports and conclusions of process *validation* and *equipment qualification studies*;
  - d) records of supply and reagent acceptance or rejection;
  - e) archived documents; and
  - f) master lists of preprinted *labels*.



- ~~10~~11) ~~Evaluation of~~ evaluating training of personnel and, where ~~possible~~ required, the *competency* of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to the *SOPM*;
- ~~11~~12) ~~Maintenance of~~ maintaining *labeling* controls, including all brochures, pamphlets, and promotional materials; and
- ~~12~~13) establishing a process for sharing information with other *tissue banks* that are known to have *recovered* and/or received *tissue* from the same *donor*.

#### **K1.200 Qualification, Verification, and Validation Requirements**

Each *tissue bank* shall:

- 1) develop, document, and implement ~~protocols shall be developed, implemented, and documented~~ for the *qualification, verification, or validation* of significant components of:
  - a) *facilities*;
  - b) *processes*;
  - c) *equipment*;
  - d) *reagents*;
  - e) *labels*;
  - f) *containers*;
  - g) *packaging materials*;
  - h) *electronic systems*; and
  - i) *donor eligibility criteria*.
- 2) perform *process validations* ~~shall be performed where the results of a~~ for *processes* whose results cannot be fully *verified* by subsequent inspection and test;
- 3) assess ~~*validations* shall be assessed when process changes are made~~ and perform *revalidation* ~~performed as~~ appropriate ~~indicated~~; and
- 4) evaluate parameters tested and determine the adequacy of the study to demonstrate necessary outcomes.

~~Determination of the frequency and which~~ Elements or items are to that must *be qualified, verified, or validated* ~~shall be made by individuals responsible for~~ *Quality Assurance* ~~and regulatory compliance. Evaluation of parameters tested shall be performed and adequacy of the study to demonstrate necessary outcomes shall be determined.~~ shall be determined from a risk assessment that has been approved by the *tissue bank's* quality department and the frequency of these activities will be determined by the risk assessment and results of the initial and follow up *validations*.

#### **K1.210 Validation Methods**

Where *validation* is required or desired, evidence supporting *validation* must be demonstrated. Acceptable methods to demonstrate *validation* are:

- 1) studies conducting challenges such as temperature, time, with indicator organisms, as appropriate, and/or other factors determined by the risk assessment that potentially affect *tissue quality*, as well as studies demonstrating consistency when the steps are repeated lot to lot; or
- 2) identification of an established *procedure* or process known to be effective, with implementation of the same *procedure* or process, without modification; such *procedure* or process shall be verified, as specified in K1.230. [For example, the implementation of a literature based *disinfection* process shall include conducting at least method suitability testing (Bacteriostasis/Fungistasis testing) per USP <71> prior to implementation (see AATB Guidance Document No. 5)]; If any steps are modified, all such modifications shall undergo documented evaluation (e.g., through a risk assessment) for potential impact, and a potential result may be that a *re-validation* is necessary per method 1 of this section.

#### **K1.210 K1.220 Packaging Qualification and Transport/Shipping Validation of Shipping Containers**

~~(C, V, CT)~~

~~Qualification studies of the transportation devices and methods for temporary storage shall demonstrate maintenance of the temperature and appropriate characteristics of the tissue at required storage temperatures for the entire requisite time.~~

Packages used to transport *recovered tissue*, to ship tissue *in-process*, or to *distribute finished tissue* shall be qualified. The method(s) used shall be validated to demonstrate that the *packages* can maintain the required conditions to meet the *finished tissue quality* at the end of its stated expiration date.

#### **K1.220 Validation Procedures—Packaging and Freezing Protocols**

~~(C, V, CT)~~

~~Packaging and freezing protocols, to meet pre-specified tissue characteristics, shall be established and documented.~~

#### **K1.230 Verification Methods**

Where *verification* is required or desired, evidence supporting *verification* must be produced by one or more of the following methods:

- 1) review, examination, inspection, or testing of a defined number of samples (the justification of the number of samples *must* be documented) in order to establish and document that the *tissue*, service or system meets specified regulatory or technical standards;
- 2) *verification* of the implementation of an established, previously *validated*, *procedure* or process without modification; *such verification* shall be conducted using a defined number of samples/processing events (the justification of the number of samples/processing events *must* be documented); or
- 3) a documented review such as when a *tissue recovery* program *must verify* that a

processor's donor eligibility criteria is compliant with federal regulations, state law, and AATB Standards.

### **K1.300 Purchasing Controls**

Each *tissue bank shall* establish and maintain *procedures* to ensure that all purchased or otherwise received products and services, including testing services, conform to specified requirements. Each *tissue bank shall* establish and maintain the requirements, including *quality* requirements that *must* be met by suppliers, contractors, and consultants. Each *tissue bank shall*:

- 1) evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation *shall* be documented-;
- 2) define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results-; and
- 3) establish and maintain *records* of acceptable suppliers, contractors, and consultants. Each *tissue bank shall* establish and maintain data that clearly describe or reference the specified requirements, including *quality* requirements, for purchased or otherwise received product and services. Purchasing documents *shall* include, where possible, an agreement in which the suppliers, contractors, and consultants agree to notify the *tissue bank* of changes in the product or service so the *tissue bank* can determine whether the changes *may* affect *quality*.

For contracted services involving donor screening, donor eligibility, tissue recovery, acquisition, collection, processing, storage, and/or distribution, refer to B1.500 for additional requirements. Also refer to specific information at B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

### **K1.310 Contracted Testing Services**

Contracted testing services may be performed remotely at the contracted laboratory or on-site at the *tissue bank*, and evaluation of testing services is expected.

### **K1.311 Types of Testing Services**

Examples of contracted testing services include, but are not limited to, the following:

- 1) donor infectious disease testing (also see B1.600);
- 2) microbiology testing (e.g., cultures on *tissue*, bioburden determination);
- 3) environmental monitoring;
- 4) sterilization validation;
- 5) irradiation dose auditing;
- 6) lot release testing (e.g., residual moisture, residual calcium, endotoxin levels);
- 7) calibration services (e.g., pipettes, temperature monitoring devices, equipment);

and

- 8) cleanroom certification.

#### **K1.312 Evaluation of Testing Services**

Each *tissue bank* utilizing outside testing services *shall* ensure the testing facility and test methods are adequate for the intended use of the test results. This evaluation *may* include, but is not limited to, the following:

- 1) FDA registration, if required;
- 2) applicable state licenses, certifications and accreditations;
- 3) maintenance of an adequate *quality assurance program* to ensure the validity of results (e.g., test sample integrity, *quality control* samples, personnel *competency*, equipment maintenance, materials management);
- 4) participation in a laboratory *proficiency testing* program, if available;
- 5) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);
- 6) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical, and/or environmental conditions);
- 7) appropriate test method selection and *validation/qualification*;
- 8) use of traceable reference materials and calibration standards, where applicable; and
- 9) results from a paper, virtual, or on-site *audit*.

### **K2.000 QUALITY CONTROL PROGRAM**

The *QA program* shall establish and maintain *QC procedures* that include the following:

- 1) *environmental monitoring*;
- 2) equipment maintenance and monitoring;
- 3) *tolerance limits*;
- 4) *in-process controls* monitoring;
- 5) reagent and supply monitoring; and
- 6) laboratory performance monitoring.

#### **K2.100 Laboratory Proficiency Testing**

~~*Proficiency testing shall be performed and encompass routine and alternate test procedures. Samples shall be tested by Responsible Persons.*~~ Laboratories shall participate in relevant *proficiency testing* programs for all analytes, if available. *Proficiency testing*

shall be conducted in accordance with the laboratories' normal testing and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

*Procedures shall incorporate a plan for remedial corrective action for poor performance on proficiency testing.*

## **K2.200 Laboratory Quality Assurance Program**

Laboratories shall establish and maintain a *quality assurance program* adequate to ensure the validity of test results. The laboratory *quality assurance program* shall include, but is not limited to, the following:

- 1) appropriate test method selection and *validation/qualification*;
- 2) monitoring/trending internal *quality control* samples;
- 3) test sample specifications and integrity (e.g., identification, transportation, type, quantity, rejection criteria, preparation, storage);
- 4) personnel qualification, training and *competency*;
- 5) equipment selection, *validation/qualification*, calibration and maintenance;
- 6) use of traceable reference materials and calibration standards, where applicable;
- 7) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical and/or environmental conditions);
- 8) materials management;
- 9) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);
- 10) result *verification*, review and release; and
- 11) *records/data* management.

## **~~K2.200~~ K2.300 Microbiological Tissue Cultures**

### **~~K2.240~~ K2.310 Pre-Sterilization/Pre-Disinfection Cultures**

Except for *reproductive tissue banks* and *skin* (S), each *tissue bank* shall establish appropriate *pre-sterilization/pre-disinfection culture* methods and sampling strategies to represent all *tissues* received from a particular *donor*. The *pre-sterilization/pre-disinfection culture* results shall be documented in the *donor's record*. See AATB ~~Interim~~ Guidance Document No. 5, ~~Standard K2.210 Pre-Sterilization/Pre-Disinfection Cultures~~ for required expectations.

If tissue *sterilization* or *disinfection* will not occur a *pre-sterilization/pre-disinfection culture* is not required, however, refer to culture requirement at K2.320.

The Medical Director or his/her physician designee [see exception that follows for (S)] shall review these *pre-sterilization/pre-disinfection culture* results prior to release of *tissue* for *transplantation*.

(MS, OA, SB)

*Tissues with pre-sterilization/pre-disinfection cultures positive for Clostridium, Streptococcus pyogenes (group A strep.), or any other microorganisms determined by the processor to be virulent or difficult to eliminate, shall be discarded unless treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms. Other individual tissues from the same donor that were recovered under conditions that could result in cross-contamination must be discarded unless they will be treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms.*

(BT, C, V, CT)

~~Standard E1.040 Sterilization/Disinfection of Tissue (C, V, CT)~~ [E2.800](#) applies.

- (S) ~~Pre-processing skin~~ Cultures from representative anatomical areas shall be obtained prior to processing. Culture methods shall be validated to ensure the suitability of the culture method selected. Inhibitory substances (e.g., skin prep solution(s), transport media, antibiotics, etc.) that may be added to unprocessed skin during recovery or for transport must not interfere with culture results. (i.e., produce false negative results) exposure of the tissue to antibiotic-containing Processing solutions or other disinfecting/sterilization methods.

~~Culture results shall be documented in the donor's record. Individual anatomic areas yielding e~~ Cultures positive for microorganisms considered to be pathogenic, highly virulent must be discarded unless the tissue can be disinfected/sterilized with a validated process (see [E2.800](#) ~~E1.040 Sterilization/Disinfection of Tissue~~). The Medical Director or designee shall review all available pre-processing skin culture results prior to releasing the tissue for transplantation. Skin recovery shall be performed as a separate zone from other tissue types so that culture results can be independently reviewed.

#### ~~K2.220~~ [K2.320](#) Final/Pre-Packaging [Cultures](#)

Except for autologous and reproductive tissues, all tissue to be released for human transplantation shall have representative microbiological cultures obtained which includes testing to detect bacteria and fungi. The results must be documented in the donor record, unless dosimetric release has occurred by a validated process according to ~~E1.042~~ [E2.820](#). Appropriate final packaging cultures (aerobic and anaerobic) shall be obtained and the results shall meet established parameters defining acceptable final packaging cultures before tissue is released for transplantation. All culture results shall be reviewed prior to release of tissue for transplantation. Any variance in the culture results from established parameters shall be reviewed and approved by the Medical Director or his/her designee prior to release. Except as described for skin (S) below, no allografts contained within the processing batch may be released for transplantation if post-processing final sterility test results show organism contamination. Allograft rework is permitted with an established program validated to eliminate the organism identified.

- (A) Except for skin, if autologous tissue is being processed, microbiologic cultures, which includes testing to detect bacteria and fungi, should be obtained immediately prior to processing.

(C, V) Representative cardiac [tissue](#) and vascular tissue samples shall be cultured

for fungal growth.

(MS, OA, SB, C, V, CT)

Microbiologic testing of *processed tissue*, which includes testing to detect bacteria and fungi, *shall* be performed on each donor *lot*.

(S) Representative fresh or *cryopreserved skin* samples *shall* be cultured for the presence of fast-growing fungal organisms. Fresh or *cryopreserved skin* *shall* not be used for *transplantation* if any one of the following is ~~noted~~ detected at final culture:

- 1) *Staphylococcus aureus*;
- 2) *Streptococcus pyogenes* (group A strep.);
- 3) *Enterococcus* sp.;
- 4) gram-negative bacilli;
- 5) *Clostridium*; and
- 6) fungi (yeasts, molds).

#### ~~K2.300~~ K2.400 Testing for Residues

(C, V) ~~Representative samples from processed tissue that have been thawed, rinsed and prepared as if for use should be~~ Initially, and as required at K1.200, each tissue bank shall thaw, rinse and prepare representative samples from processed tissue as if for use and ~~tested them~~ to evaluate the concentration of residual cryoprotectant(s) (if applicable), ~~initially and after any change in Processing.~~

#### ~~K2.400~~ K2.500 Other Quality Control Procedures

##### ~~K2.410~~ K2.510 Lyophilized/Dehydrated/Desiccated Tissue

~~(MS) QC programs for monitoring performance of either a lyophilizer, or a dehydrator or desiccator shall be documented~~ established and verified for each batch. When a residual moisture limit has been established, Either one a representative sample that demonstrates the worst-case scenario for that batch for each type of tissue dried or duplicate cortical bone samples from each drier run shall be tested for residual moisture and shall not exceed the limit. Refer to E2.710 and E2.720.

##### ~~K2.420~~ K2.520 Annual Calibrations

Each tissue bank shall ensure at least annual calibration of mechanical devices used for storage shall be subjected to no less than annual calibration with a National Institute of Standards and Technology-traceable thermometer. The overall QA program shall include maintenance of calibration records. ~~shall be maintained as part of the overall QA program.~~

### K3.000 MICROBIOLOGIC TESTING

All microbiologic ~~cultures~~ testing of *tissue* to be released for *transplantation* *shall* be performed by a



qualified laboratory using appropriate test methods. If microbiologic testing is to be performed by the tissue bank, the requirements at K2.100 and K2.200 shall apply. that is either certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) or is certified or accredited by another laboratory accrediting organization that has deemed status for CLIA (the College of American Pathologists, The Joint Commission, certain state licensure). If the services of an outside laboratory are used, the requirements at K1.300 and K1.310 shall apply. procedures used by that laboratory and results of testing by that laboratory shall be reviewed by the *Responsible Person* at the tissue bank and recorded in the donor's record. The facility must also have a procedure in their *SOPM* for determining the acceptability of outside testing laboratories.

If microbiologic testing is to be performed by the tissue bank, the requirements as outlined in Standards E1.900-E1.920 (In-House Laboratory Testing, Laboratory Records, and Laboratory Controls) shall apply and the Tissue Bank must ascribe to proficiency testing programs and/or certification to appropriate ISO Standards.

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding qualification of laboratories via accreditation, designation, authorization and/or licensure.

### **K3.100 Transport Medium**

~~The *Transport Medium* shall be such that it maintains the viability of aerobic and anaerobic, bacterial and fungal organisms.~~

### **K3.200 Selection of Growth Medium**

~~Microbiologic growth media should be carefully selected to provide the optimal conditions to support the growth of aerobic and anaerobic, bacterial and fungal organisms commonly encountered from a particular site or type of specimen.~~

### **K3.210 Quality Control of Growth Medium**

~~Tissue banks or contracted microbiology laboratories shall follow standards developed by the Clinical and Laboratory Standards Institute (CLSI) specifying the requirements for *Quality Assurance* testing of culture media (QA for Commercially Prepared Microbiological Culture Media, M22-A).~~

~~Media that has been purchased commercially does not require in-house QC testing; however, the testing laboratory should receive, along with each new *Lot* of media purchased from the manufacturer, a statement indicating that the medium meets the standards of the CLSI or any equivalent standards. These manufacturer's statements shall be retained for at least 10 years as QC records for each batch of medium.~~

~~Tissue banks that prepare their own growth medium must perform the following QC checks on each batch of media prepared:~~

- ~~1) Each batch of media that is autoclaved or filtered during preparation shall be checked for sterility; a sample of the batch is sufficient for this check; and~~
- ~~2) Each batch of media shall be checked for ability to support growth, using *Staphylococcus aureus* ATCC 25923 to check for aerobic growth; and *Bacteroides fragilis* ATCC 23745 or 25285 for anaerobic growth.~~

~~If the batch or Lot is not used within 30 days, another check is recommended.  
Records must be kept for all QC procedures listed above. Batches of media that do not meet  
the above criteria shall not be used.~~

### ~~K3.300~~ **K3.100 Microbiologic Subcultures**

~~The testing lab shall subculture a~~ Any positive microbiologic culture; ~~(as demonstrated by conventional criteria or automated instrumentation), shall have~~ to identify the organism(s) identified to the by genus, and ~~, where appropriate, the species level~~ where appropriate.  
See Guidance Document No. 5.

## **K4.000 INVESTIGATIONS**

The QA program shall ~~provide for~~ ensure the there is an investigation and review for completeness ~~conclusion of investigation of accidents, errors, complaints, deviations, and adverse outcomes.~~ Investigation shall include a summary report, precipitating events, recommendations, and resolutions shall be documented in a summary report by the staff involved and reviewed for completeness by the QA Program. The QA program shall retain for 10 years ~~All~~ all reports generated shall ~~be retained on file for 10 years.~~

### **K4.100 Errors and Accidents**

The QA program shall ensure a documented investigation of any errors and or accidents in obtaining informed consent or authorization, in donor screening, collection, acquisition, or tissue recovery, processing, quarantining, releasing, labeling, storing, and distribution or dispensing, ~~shall be investigated and documented.~~ If the error or accident ~~has medical consequences or~~ may affect the safety of the tissue to be released or that has been released, the Medical Director or licensed physician designee shall also review and evaluate the incident. When tissue may have been contaminated, the QA program shall ensure the documented review and evaluation both of processing procedures ~~shall be reviewed and of any~~ any other tissue processed simultaneously or from the same donor ~~shall be evaluated.~~

### **K4.200 Complaints**

The QA program shall ensure that a All written and oral complaints regarding tissue quality, safety, packaging, or effectiveness ~~shall be~~ are expeditiously investigated to determine whether the complaint is related to an error, accident, adverse outcome, or other factor, unless such investigation has already been performed for a similar complaint. If it is determined that no investigation is necessary, ~~the tissue bank~~ a responsible person shall ~~maintain a record that includes~~ document the reason that no investigation was made and the name of the individual responsible for the decision not to investigate. Each investigation shall determine whether associated tissue may be affected. If it is determined that they may be affected, then those associated tissue ~~tissues~~ shall be located and quarantined until resolution of the incident (which may involve initiation of a recall ~~or Field Notification~~). The Medical Director or licensed physician designee shall review complaints that are medical in nature ~~shall be reviewed by the Medical Director or licensed physician designee.~~

When an investigation is made, a record of the investigation shall include:

- 1) the date the complaint was received;
- 2) the name of the tissue;

- 3) the unique tissue identifier identification number;
- 4) the name, address, and phone number of the complainant;
- 5) the nature and details of the complaint;
- 6) the dates and results of the investigation;
- 7) any corrective action taken; and
- 8) any reply to the complainant.

#### **K4.300 Adverse Outcomes**

The QA program shall ensure that all ~~All~~ reported adverse outcomes that are potentially related, directly or indirectly, to an allograft ~~shall be~~ are investigated thoroughly and expeditiously. The Medical Director or licensed physician designee shall review all potential adverse outcome reports and participate ~~be involved~~ in determination of the impact and resolution of any adverse outcome. If investigation indicates that the adverse outcome is related to an error or accident, then the tissue bank shall follow procedures for errors and accidents (see K4.100) ~~shall also be followed~~.

#### **K4.310 Reporting**

The QA program shall ensure that all cases of transmissible disease in a recipient attributed to the allograft ~~shall be~~ are reported in writing ~~in a timely fashion to~~ as required by public health authorities, and in a timely fashion to organ procurement organizations and tissue banks involved in any manner with tissue recovered from the same donor and to the physician(s) involved in the transplantation of tissue from that donor. Reporting ~~shall~~ be documented in the donor's record.

See the Accreditation Policies for Transplant Tissue Banks for other required reporting.

#### **K5.000 INTERNAL AUDITS**

All tissue banks shall establish policies and procedures regarding the scope and frequency of routine and focused QA audits. ~~The Self-assessment Tool/Audit Report (STAR) must be completed annually and documented on a form provided by, or pre-approved by, the AATB Director of Accreditation (refer to the AATB Accreditation Policies for Transplant Tissue Banks).~~ The QA program staff shall perform audits, at least annually, of the major tissue banking operational systems to identify trends or recurring problems in: donor evaluation and acceptance; tissue recovery or collection, processing, preservation and packaging; donor and tissue testing; quarantining; labeling; storage; distribution; electronic systems; and records management. The QA program shall perform focused audits ~~shall be conducted to monitor~~ of critical areas (unless the annual routine audit covers all critical areas); and of any area with a pattern of quality ~~they shall also be conducted when problems with quality have been identified~~. If the routine or focused audit is not conducted by the QA Program staff, the All audits shall be performed by persons who do not have direct responsibility for the process being audited. The tissue bank shall take corrective action(s) when necessary, including a re-audit of deficiencies; ~~shall be taken when necessary~~. A The QA program staff shall document and report ~~of the~~ dates and results of each quality audit, (and re-audit) to management responsible for the audited systems, who shall review each report(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the systems audited.

~~The dates and results of quality audits and re-audits shall be documented.~~

## **K6.000 EXTERNAL AUDITS**

External audits may be indicated for certain services, suppliers, contractors, and consultants. See K1.300 and B1.521.

## **~~K6.000~~ K7.000 ELECTRONIC SYSTEMS CONTROLS**

### **~~K6.100~~ K7.100 Authorized Access**

Each tissue bank shall exercise appropriate controls ~~shall be exercised~~ over *electronic systems* to assure that ~~limit~~ general access is limited to authorized personnel and that to permit only authorized personnel to alter changes in master production and control *records* or other ~~records are instituted only by authorized personnel.~~

### **~~K6.200~~ K7.200 Error Reduction**

When automated data processing is used for decision-making in *processing*, adequate procedures shall be designed and implemented to prevent inaccurate input or output of data and programming *errors*.

### **~~K6.300~~ K7.300 Backup Files**

A backup file ~~should~~ shall be maintained of all data that are entered into an *electronic system* and subsequently used for decision-making purposes, and of all data that are not otherwise *recorded* and accessible.

### **~~K6.400~~ K7.400 Security**

*Electronic systems* shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.

### **K7.500 Audit Trail**

Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision.

## SECTION L TISSUE DISPENSING SERVICES

~~Words that are defined in A2.000 Definitions of Terms appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.~~

### L1.000 TISSUE DISPENSING SERVICES—GENERAL

Medical, dental, and hospital facilities, and physician offices that are *tissue dispensing services* shall establish policies and *procedures* ~~regarding *tissue receipt*, *storage*, and *final disposition*~~ to ensure the safety and traceability of *tissue* from receipt through *storage and final disposition such as clinical use transplantation*, ~~transfer~~ *further distribution*, or destruction.

#### L1.100 Responsibilities

Activities of a *tissue dispensing service* shall be supervised by a physician, dentist, podiatrist, or other qualified medical professional.

### L2.000 STORAGE

#### L2.100 General

*Tissue storage* shall be in conformance with *labeling materials* ~~guidelines established by the *distributing tissue bank*.~~

#### L2.200 Equipment

Freezers and refrigerators shall be regularly maintained, calibrated, and monitored using *QC* written *procedures*.

#### L2.300 Labeling

*Tissue* shall not be *relabeled*. Existing *labels* shall not be altered.

### L3.000 ~~RELEASE~~ DISPENSING, FURTHER DISTRIBUTION AND DISPOSAL

#### L3.100 Dispensing

*Tissue* shall not be dispensed for use in *recipients* without an order from a physician or other authorized health professional. Human *tissue* shall not be offered or dispensed for *veterinary use*. *Tissue* shall be transported and prepared for *transplantation* in accordance with *labeling materials* ~~the source *tissue bank's* written *procedures* and *directions*~~. All associated *labeling material*, including the *package insert*, shall be made available to the *end-user* physician and/or other qualified medical professionals.

#### L3.200 ~~Release to Another Tissue Dispensing Service or Tissue Distribution Intermediary~~

~~When a *tissue bank* forwards *tissue* obtained from another *tissue bank* or *tissue distribution intermediary*,~~ When *further distributing tissue*, all accompanying original *labeling materials* or other enclosures shall be forwarded with the *tissue*. A record shall be made ~~of such transfers,~~ including of the type and quantity of *tissue*, *tissue identification number(s)*, redistribution ~~date of transfer,~~ and destination.

### **L3.300 Tissue Disposal**

*Tissue* that is unused, partially used, or expired, damaged or otherwise unsuitable for *distribution* shall be disposed of in such a manner as to minimize any hazards to staff or the environment, in conformance with applicable laws and regulations. When applicable, the tissue dispensing service shall notify the tissue bank, or the tissue distribution intermediary from whom the tissue was obtained, of the final disposition of the tissue. Documentation of such notification shall be recorded.

#### (A) Disposal of autologous tissue shall consider the following:

- 1) there shall be a written policy for the discard of autologous tissue;
  - 2) the tissue dispensing service, in consultation with the patient-donor's autologous donor's physician, shall approve discard of the tissue, and shall be responsible for documentation of the method and date of discard; and
  - 3) ~~should not be retained beyond the expiration date, unless relabeled for research or QC purposes or otherwise indicated by the tissue bank Medical Director.~~ autologous tissue should not be used for transplantation after the expiration date.
- (R) There shall be a written policy for discard of For reproductive tissue from a client depositor or directed donor. ~~tissue discard and disposal shall be authorized by The reproductive tissue bank, the tissue donor, and/or their designees~~ shall approve discard of reproductive tissue from anonymous donors and shall document the date of discard.

### ~~**L3.400 Return of Tissue**~~

- (R) ~~Cryopreserved donor reproductive tissue that has been released to a physician or designee and subsequently not used and returned to the Reproductive Tissue Bank in the frozen state shall not be redistributed for use by any other physician or designee.~~

## **L4.000 RECORDS**

*Tissue dispensing services shall concurrently record all steps in the receiving, storage, and dispensing of tissue so that all steps can be clearly traced. Records shall be maintained for a minimum of ten years after expiration of the tissue or, in the case of tissue with no expiration date, ten years after dispensing.*

### **L4.100 Tissue Receipt Records**

Each *tissue* specimen shall have a *tissue identification number*. *Tissue receipt records shall contain, at a minimum, the following information:*

- 1) name and address of tissue supplier;
- 2) description of tissue and quantity received;
- 3) date of tissue receipt;
- 4) condition of tissue upon receipt; and
- 5) expiration date, if applicable, of tissue.

#### **L4.200 Dispensing Records**

*Disposition of tissue shall be documented. When tissue is dispensed for transplantation, the following information shall be recorded:*

- 1) name, address, and telephone number of the *tissue bank* ([tissue supplier or tissue processor](#)) ~~from whom the tissue was obtained~~;
- 2) type and quantity of *tissue* and unique *tissue identification number(s)*;
- 3) *recipient's* name and medical *record* number, or social security number or similar unique identifier;
- 4) transplantation site and date and time of release;
- 5) name of the ordering physician or other authorized health professional;
- 6) name of the person dispensing the *tissue*; and
- 7) name of the person preparing the *tissue(s)* for use, if *tissue* is prepared at the site of dispensing.

This information *shall* be maintained in the *tissue dispensing service records* in a log format. The *tissue recipient's* medical *records* *shall* contain, at a minimum, the first five items to permit tracing of each *tissue* from the ~~source-tissue bank~~ ([tissue supplier or tissue processor](#)) to each *recipient*.

The *tissue bank's* *tissue tracing* forms *shall* be completed, specifying the *disposition* of the *tissue*, and returned [as instructed in labeling materials](#) ~~to the tissue supplier~~.

#### **L5.000 ADVERSE OUTCOMES**

Potential adverse reactions, suspected transmission of disease, or other complications, directly or indirectly related to the *allograft*, *shall* be reported [as instructed in labeling materials](#) ~~to the tissue-processor~~ and thoroughly investigated and documented.

#### **L6.000 [FIELD](#) CORRECTIONS AND REMOVALS**

The *tissue dispensing service* *shall* have specific written policies and *procedures* for the performance of a [field](#) *correction* or *removal*, if applicable. *Procedures* *shall* include, but are not limited to, the following:

- 1) designation of a *responsible person(s)*;
- 2) location and *quarantine* of affected inventory, in a timely manner;
- 3) communication with the *tissue bank* ([tissue supplier or tissue processor](#) ~~manufacturer, tissue source-facility~~);
- 4) communication with the *end-user*; and
- 5) documentation and *record* requirements.



## SECTION M

### TISSUE DISTRIBUTION INTERMEDIARIES

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#### ~~M1.000~~ TISSUE DISTRIBUTION INTERMEDIARIES—GENERAL

An agent who acquires *distributed tissue* for *storage* and further *distribution* shall establish policies and *procedures* ~~regarding receipt, storage, and final disposition of tissue~~, to ensure the *safety* and *traceability* of *tissue* from receipt through *storage*, clinical use, ~~transfer~~ *further distribution*, or destruction. See relevant parts of Section B and Section J.

NOTE: When any *tissue banking* activities are performed beyond the few functions that identify an entity as a *tissue distribution intermediary* (i.e., an agent that only acquires and *stores tissue* for *further distribution*), relevant *tissue bank* standards apply and compliance is required for accreditation. *Tissue bank* functions that surpass functions solely under the definition of a *tissue distribution intermediary* include:

- 1) *designing, creating, maintaining, or controlling the specifications for finished tissue*, relevant parts of Section E apply (e.g., the *series of standards* at E2.600 and E2.421);
- 2) *designing, creating, specifying, or maintaining responsibility for the contents of the label for finished tissue*, relevant parts of Section G apply;
- 3) *performing any labeling functions to include the physical application of a label to finished tissue*, relevant parts of Section G apply; and/or
- 4) *final review for tissue release*, relevant parts of Section F apply (e.g., F1.300, *series of standards* at F4.000).

#### M2.000 STORAGE

##### M2.100 General

*Tissue storage* shall be in conformance with the *package insert and monitoring expectations*, *guidelines* established by the distributing tissue bank. See E3.330, E3.331, E3.340, and C1.300.

##### M2.200 Equipment

Freezers and refrigerators *shall* be regularly maintained, calibrated, and monitored according to written *QC procedures*. See the *series of standards* at J5.000.

#### ~~M2.300 Labeling~~ M3.000 LABELING

*Tissue* shall not be *relabelled*. Existing *labels* shall not be altered. *Additional labels shall not be applied unless pre-approved by the tissue bank processor that applied the original label*. Refer to the *series of standards* at G1.000.

#### ~~M3.000~~ M4.000 DISTRIBUTION—GENERAL

There *shall* be written *procedures* for the receipt of *tissue* orders, unit selection, final *container*, and/or *package* inspection, shipping, and transportation of *tissue* for *transplantation*. When a *tissue distribution intermediary* forwards further distributes *tissue*, all accompanying *labeling materials* or other enclosures *shall* be forwarded with the *tissue*.

#### ~~M3.100~~ M4.100 Tissue Distribution Restrictions

Provision of *tissue* for *transplantation* *shall* be restricted to hospitals, free-standing medical facilities, *tissue banks*, *tissue dispensing services*, another *tissue distribution intermediary*, and *end-users* (e.g., physicians, dentists, podiatrists or other medical professionals) for use in *recipients* with the *veterinary use exception that follows*. ~~*Distribution of tissue for transplantation shall be restricted to requests from tissue banks and Tissue Dispensing Services for use in Recipients. Tissue distribution intermediaries shall have procedures that describe evaluation of requests from new customers for tissue. Human tissue for transplantation shall not be offered or distributed for veterinary use unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or informed consent.*~~

#### ~~M3.200~~ M4.200 Distribution to Another Tissue Distribution Intermediary ~~Transfer of Tissue to Other Tissue Banks/Dispensing Services~~

If *tissue* is distributed to another *tissue distribution intermediary*, that *tissue distribution intermediary* shall meet the requirements of Section M.

#### ~~M3.300~~ M4.300 Requests for Donor Status and Tissue Processing Information

*Donor* risk assessment, *tissue* condition(s), and *tissue processing* details, with the exception of information that may infringe upon the confidentiality of *donor* information, *shall* be made available to the *transplanting* physician upon request.

### M5.000 CONSIGNMENT INVENTORY MANAGEMENT

If *tissue* is provided on *consignment*, the *tissue distribution intermediary* shall maintain *procedures* to ensure *traceability* and that appropriate *storage* conditions are maintained during *consignment*, further *distribution* or return.

#### ~~M3.400~~ Distribution Records

~~*Tissue Distribution Intermediaries* shall maintain *Distribution* records. These records shall be designed to permit *tissue* to be traced from the donor to a *Consignee* or *End User*, and from a *Consignee* or *End User* back to the donor. Records shall indicate the final *Disposition* of all *tissue* handled by a *Tissue Distribution Intermediary*. *Tissue Distribution* records shall include, but not be limited to:~~

- ~~1) Date of order placement;~~
- ~~2) Name and address of *Consignee*;~~
- ~~3) Name of the individual placing the order;~~
- ~~4) Type and quantity of *tissue* ordered; and~~
- ~~5) Information pertaining to *tissue* selected for shipment, including:~~

- a) Identification number(s) of tissue;
- b) ~~Collection or expiration date of the tissue;~~
- c) ~~Date of shipment;~~
- d) Type and amount (if applicable) of refrigerant used for shipment;
- e) Mode of transportation; and
- f) Name of the staff member filling the order.

Prior to *Distribution*, the labeled tissue shall be reviewed to verify that tissue has been properly identified and labeled. Such inspection shall be documented.

### **~~M3.500 Tissue Disposal~~**

~~Unused, partially used, or expired tissue shall be disposed of in such a manner as to minimize any hazards to staff or the environment in conformance with applicable laws or regulations.~~

~~The Tissue Distribution Intermediary shall notify the tissue bank of the final Disposition of the tissue and all actions taken must be documented.~~

## **~~M4.000~~ M6.000 PACKAGING AND SHIPPING**

### **~~M4.100 Tissue Storage Environment~~**

~~If specific environmental conditions are required for storage of tissue, maintenance of those conditions during transit shall be required. Specific environmental conditions shall be in accordance with the SOPM and these Standards.~~

### **M6.100 Pre-Shipping Inspection**

Prior to shipping, packages shall be inspected to ensure the external packaging and labels are undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. The exterior of the transport package shall be inspected to verify that requirements in G3.310 are met. These inspections shall be documented, including identification of staff conducting inspections.

### **~~M4.200~~ M6.200 Validation and Packaging Expiration**

If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport ~~container~~ package to maintain the required environmental conditions shall be demonstrated and documented in a validation study. The length of time those conditions can be maintained by the packaging (assuming normal handling) shall also be determined. Expiration dates of the packaging shall be noted on the outside of the ~~shipping~~ transport package.

### **~~M4.300 Quality Control~~**

~~If tissue to be shipped requires specific environmental conditions other than room-temperature, periodic Quality Control monitoring of shipping and packaging must be performed to verify capability to maintain the required environmental conditions for the~~

defined time periods.  
These QC checks shall be documented.

#### **M4.400 Final Inspection**

All packages shall be subjected to a final inspection to verify that the *Containers* are intact, the labels are complete, the *Package Insert* is present, and each transport container is sufficient for the type and requirements of the tissue being shipped. The exterior of the transport container shall be inspected to verify that the name and address and telephone number of the distributing facility and the name and telephone number of the *Consignee* are present. *Verification* that any hazardous materials, type of refrigerant used, transport (shipping) expiration date (if applicable) and prominent identification as “DONATED HUMAN TISSUE,” is clearly visible.

#### **M4.500 M6.300 Transportation**

The mode of transportation selected *shall* be determined by any special shipping and handling requirements of the *tissue* and/or shipping refrigerants, shipping restrictions of commercial carriers, and the urgency of the *tissue* request.

##### **M6.310 Domestic Shipments**

The transport package label shall include the following information:

- 1) name, address and telephone number of the ~~distribution facility~~ tissue distribution intermediary;
- 2) name and address, and telephone number of the consignee or end-user;
- 3) prominent identification of contents as “DONATED HUMAN TISSUE.” Note: If the reproductive tissue in the shipment was collected from a client depositor, prominent identification as “HUMAN TISSUE”;
- 4) recommended storage conditions and transport expiration date (if applicable);
- 5) type and quantity of refrigerant or other hazardous materials enclosed in the transport package;
- 6) transport (shipping) expiration date (if applicable), and
- 7) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).

##### **M6.320 International Shipments**

Labels for international shipments shall contain all of the information required for domestic shipments; however, information may be modified to meet requirements of the federal government and those of the receiving country.

#### **M5.000 M7.000 RETURN OF TISSUE**

A tissue distribution intermediary shall establish a policy authorizing or prohibiting the return of

*tissue* in its original, unopened *container*. If returns are permitted, the integrity of the *container*, *transport package*, and *labeling* shall be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required *storage* temperatures, *tissue* shall not be returned to *distribution* inventory. Information pertaining to the return of *tissue* shall be recorded in the *disposition records* for that *tissue* as follows:

- 1) *documentation* of *container* examination;
- 2) *documentation* of *end-user storage* and shipping conditions;
- 3) *reason* for the return;
- 4) *disposition* of the returned *tissue*; and
- 5) *date* and name of the staff member who evaluated and determined the *disposition* of the *tissue*.

#### ~~M6.000~~ **M8.000 FIELD CORRECTIONS AND REMOVALS —GENERAL**

The need to perform a *field correction* or *removal* may be identified as a result of a *complaint*, *adverse outcome*, *accident*, *error*, *deviation*, *audit*, or by any other means. (For the applicable *quality assurance* requirements, see *relevant parts of Section K*. An evaluation to determine if *field correction* or *removal* is warranted *should* be made whenever *distributed tissue* may not meet specifications related to *safety*, *quality*, *identification*, *function* and/or *use*. This evaluation *must* consider both risk to health posed by the *tissue* and applicable regulatory requirements, and be documented.

*Tissue distribution intermediaries* shall have specific, written policies and *procedures* for the performance of a *field correction* or *removal*. Procedures *shall* include, but are not limited to, the following:

- 1) *designation* of a *responsible person(s)*;
- 2) *location* and *quarantine* of affected inventory, in a timely manner;
- 3) *communication* with the *tissue bank* (*tissue supplier or tissue processor manufacturer, tissue source facility*);
- 4) *communication* with the *end-user*; and
- 5) *documentation* and *record* requirements.

#### ~~M6.100~~ **M8.100 Field Correction and Removal Records**

All information relating to the *field correction* or *removal* of *tissue* and resulting communications *shall* be documented and retained on file for at least 10 years beyond the date of *distribution*, the date of *transplantation* (if known), *disposition*, or expiration of the *tissue*, whichever is latest. The file *shall* include, but not be limited to:

- 1) *reason* for the *field correction* or *removal*;
- 2) *identification* and *location* of affected *tissue* in a timely manner, including *quarantine* steps;
- 3) *steps* taken to correct or retrieve *tissue*;

- 4) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of *field notifications* or letters and a list of those to whom notice was sent);
- 5) final *disposition* of the *tissue*;
- 6) corrective *actions* recommended and implemented; and
- 7) documentation of review.

## **~~M7.000~~ M9.000 RECORDS**

The *tissue distribution intermediary* shall concurrently *record* all steps in the receiving, *storage*, and dispensing of *tissue* so that all steps can be clearly *traced*. *Records* shall be maintained for a minimum of ten years after the expiration date of the *tissue*, or in the case of *tissue* with no expiration date, ten years after *distribution*. See applicable requirements of Section C.

### **M9.100 Tissue Receipt Records**

Each finished tissue specimen shall have a tissue identification number. Tissue receipt records shall contain, but not be limited to, the following information:

- 1) name and address of tissue supplier;
- 2) description of tissue and quantity received;
- 3) date of tissue receipt;
- 4) condition of tissue upon receipt; and
- 5) expiration date, if applicable, of tissue.

### **M9.200 Distribution Records**

Tissue distribution intermediaries shall maintain distribution records. These records shall be designed to permit tissue to be traced from the donor to a consignee or end-user, and from a consignee or end-user back to the donor. Records shall indicate the final disposition of all tissue handled by a tissue distribution intermediary. Tissue distribution records shall include, but not be limited to:

- 1) date of order placement;
- 2) name of the site to which the tissue is distributed;
- 3) name of the individual placing the order;
- 4) type and quantity of tissue ordered; and
- 5) information pertaining to tissue selected for shipment, including:
  - a) identification number(s) of tissue;

- b) collection or expiration date of the *tissue*;
- c) date of shipment;
- d) type and amount (if applicable) of refrigerant used for shipment;
- e) mode of transportation; and
- f) name of the person releasing the *tissue*.

Prior to *distribution*, the *labeled tissue* shall be reviewed to *verify* that *tissue* has been properly identified and *labeled*. Such inspection *shall* be documented.

Any completed *tissue tracing* forms, specifying the *disposition* of the *tissue*, shall be returned to the ~~tissue supplier~~ as instructed in *labeling materials*.

### **M9.300 Tissue Disposal**

Unused, partially used, or expired *tissue* shall be disposed of in such a manner as to minimize any hazards to staff or the environment in conformance with applicable laws or regulations. The *tissue distribution intermediary* shall notify the *tissue bank* of the final *disposition* of the *tissue* and all actions taken *must* be documented.

### **~~M7.100 Tissue Receipt Records~~**

~~Each tissue specimen shall have a *Tissue Identification Number*. Tissue receipt records shall contain, but not be limited to, the following information:~~

- ~~1) Name and address of tissue supplier;~~
- ~~2) Description of tissue and quantity received;~~
- ~~3) Date of tissue receipt;~~
- ~~4) Condition of tissue upon receipt; and~~
- ~~5) Expiration date, if applicable, of tissue.~~

### **~~M7.200 Distribution Records~~**

~~When tissue is transferred to another facility, the following information shall be recorded:~~

- ~~1) Name, address and telephone number of the source tissue bank;~~
- ~~2) Type and quantity of tissue and unique *Tissue Identification Number(s)*;~~
- ~~3) Name of the person releasing the tissue;~~
- ~~4) Name of the site to which the tissue is distributed; and~~
- ~~5) Date of *Distribution*.~~

~~Any completed tissue tracing forms, specifying the *Disposition* of the tissue, shall be returned~~



~~to the tissue supplier.~~

**M8.000 M10.000 ADVERSE OUTCOMES**

Reports of *adverse outcomes*, transmitted disease, or other complications *shall* be [documented and](#) reported to the ~~supplier of the tissue~~ [processor](#) in a timely fashion and in accordance with applicable laws or regulations.

## Appendix I: REQUEST FOR VARIANCE FROM STANDARDS

### Introduction

AATB-accredited *tissue banks* may request a *variance* when a policy, process, or *procedure* is in conflict with requirements in current AATB *Standards*. A *variance* request may be submitted for specific AATB standards appearing in this edition or in announced, approved updates to this edition. AATB-accredited *tissue bank* may request a *variance* to *Standards* but may not violate current *Standards* by implementing the change without first receiving notice of written approval from the AATB Executive Office.

A *tissue bank* seeking initial AATB accreditation ~~for the first time may~~ submit a *variance* request ~~for operations being performed prior to applying for accreditation~~ with a completed application for accreditation. A request for *variance* to *Standards* cannot be submitted when noncompliance is discovered during application for re-accreditation, and such a request cannot be used as a *corrective action* in response to a *nonconformity* cited at an AATB accreditation inspection.

Requests for *variance* cannot be acted upon if they are sent by an entity that is not an AATB-accredited *tissue bank*, or has not applied for AATB accreditation.

The timeline for reviewing a request for *variance* can be affected by additional requests for information by those who review the submission as well as by the time associated with response(s) by the requestor. The burden is on the *tissue bank* to provide supporting documentation that adequately describes how the proposed practice will meet the ultimate intent of *Standards*.

### Process

#### SUBMISSION:

- 1) *Tissue banks* requesting a *variance* from current *Standards* must provide the following information to the AATB ~~Chief Policy Officer~~ Senior Vice President of Policy by using the Request for Variance to AATB Standards Submission Format that follows. The format *must* be completed in entirety and include:
  - a) the request for *variance*, including the particular standard number(s) that apply to the request;
  - b) justification of the alternative *procedure(s)*, policy or process which assure(s) equivalency to the intent of *Standards*; and
  - c) supporting information such as worksheets, records, data, or other information (e.g., *validation* of the process protocol to be used in support of the *variance* or modification, including the scientific data and *quality assurance* steps). All data and proprietary information provided to the AATB by the *tissue bank* in connection with a request for *variance* shall be treated in accordance with AATB's policy governing confidential and proprietary information.
- 2) Within thirty (30) days of a request for *variance*, the ~~Chief Policy Officer~~ Senior Vice President of Policy and the Chairperson of the Standards Committee will review the information submitted for applicability and completeness. These individuals may:
  - a) request more information to complete the submission;
  - b) ~~and may~~ consult with officers of appropriate committees and/or councils; and/or
  - c) determine the submission does not satisfy requirements for a request for *variance*.

## REVIEW:

- 1) The ~~Chief Policy Officer~~ [Senior Vice President of Policy](#) will forward the request and supportive information to the Standards Committee. These documents *may* or *may* not be blinded, depending on the nature of the submission and whether withholding the *tissue bank's* identity could adversely affect appropriate review of their submission. This decision will be made in consultation with the person who submitted the *variance* request.
- 2) *Variances* are reviewed without prejudice, and individuals involved in the preparation of the request or who have any conflict relating to the request are to exclude themselves from committee or council discussion. Subject matter experts *may* be sought for consultation at the discretion of the Standards Committee Chairperson and/or Board of Governors.
- 3) At the next scheduled meeting, the Standards Committee will review and evaluate the acceptability of the request.
  - a) If adequate information has been received, the Standards Committee *may* vote to approve or disapprove the request. Within thirty (30) days, this recommendation will be forwarded to the Board of Governors.
  - b) If additional information is required, the ~~Chief Policy Officer~~ [Senior Vice President of Policy](#) or Chairperson will request information directly from the contact person who submitted the request.

The Standards Committee *may* determine that the request *must* be reviewed by another committee or council, or *may* seek consultation with other subject matter experts. For example, requests of a scientific nature *may* be forwarded to the Scientific and Technical Affairs Committee for review and recommendation, and those of a medical nature *may* be forwarded to the Physicians' Council for review and recommendation.

If consultation with another committee or council has been requested, the recommendation regarding the request *shall* be sent to the Standards Committee Chairperson and ~~Chief Policy Officer~~ [Senior Vice President of Policy](#) within sixty (60) days of receipt. This time period *may* be extended if additional supportive information is desired by reviewers, but *should* be no longer than ninety (90) days from receipt.

Within thirty (30) days of receipt of the recommendation from another committee, a council, or subject matter expert(s), the Standards Committee will forward its recommendation, and rationale that supports the recommendation, to the Board of Governors.

## RESPONSE:

- 1) Within thirty (30) days of its receipt of the Standards Committee's recommendation, the Board of Governors *shall* take formal action on the request for *variance* and *shall* issue a written response to the *tissue bank* regarding its request. Requests for *variance* *may* be approved, delayed pending receipt of more information requested by the Board of Governors, rejected, or approved in modified form.
- 2) The Standards Committee *shall* provide notice of action on a request for *variance* to the Accreditation ~~Program~~ Manager for placement in the *tissue bank's* file.

The Board of Governor's action on a request *shall* be communicated by the ~~Chief Policy Officer~~ [Senior Vice President of Policy](#) to the Chairperson of each committee and/or council that reviewed the

request.

Notice of the grant or rejection of a *variance* from the *Standards* shall ~~may~~ be [included in AATB published materials or reports](#), ~~in the AATB Newsletter.~~

~~OTHER CONSIDERATIONS~~ [APPROVED VARIANCES](#):

- ~~1) All data and proprietary information provided to the AATB by the Tissue Bank in connection with a request for *Variance* shall be treated in accordance with AATB's policy governing confidential and proprietary information.~~
- 2) A *variance* from *Standards* may not be implemented by the *tissue bank* until the request for *variance* has been approved by the Board of Governors.
- 3) Any *Variance* from *Standards* approved by the Board of Governors is applicable only to the Tissue Bank that requested the *variance*. [It may also be applicable to a tissue bank performing activities directly related to the approved variance under written agreement/contract with the requesting tissue bank.](#)
- 3) Should the Standards Committee consider the *variance* to have universal application, the Standards Committee may recommend that the Board of Governors make the approved *variance* applicable to all accredited members under such conditions as may be prescribed.
- 4) [A record of the approved variance must be maintained at the requesting tissue bank as well as at any other accredited tissue bank directly affected by the approval. Evidence of approval of the request for variance must be available during an accreditation inspection.](#)
- 5) [Approved](#) ~~variances is granted, it shall~~ remain in effect until:
  - a) the *variance* is rescinded;
  - b) the applicable standard, ~~law or regulation~~ on which the *variance* is based, ~~are~~ [is](#) amended or deleted thereby rendering the *variance* null and void; or
  - c) the *variance* becomes meaningless due to changes in other circumstances.

**Request for Variance to AATB Standards (current edition)**  
**— Submission Format —**

**Standard for which a *variance* is submitted**

Standard number and title:

Enter current text of standard:

**Reason**

Describe justification of *variance* request:

**Supporting Information**

Attach worksheets, records, data, or other documentation that supports your request. List them here by title.

**Accredited Tissue bank Name & Representative**

(This is the contact person for this request)

Name:

Title:

Accredited *tissue bank* name:

Email address:

Phone number:

**Statement of Tissue Bank Representative**

I request that for purposes of AATB accreditation our *tissue bank should* be granted a *variance* from this standard.

Signature:

Date Submitted:

**Appendix II:**  
**CRITERIA FOR PREVENTING TRANSMISSION of RCDADs**  
**(Relevant Communicable Disease Agents and Diseases)<sup>1</sup>**  
**THROUGH TRANSPLANTATION OF HUMAN TISSUE**

**Behavior/History Exclusionary Criteria:**

- 1) men who have had sex with another man within the preceding five years;
- 2) persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections;
- 3) persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates in the preceding five years;
- 4) persons who have had sex in exchange for money or drugs in the preceding five years;
- 5) persons who have had sex in the preceding 12 months with any person described in the 4 items above or with any person who has HIV infection, including a positive test for HIV, hepatitis B infection, or clinically active (symptomatic) hepatitis C<sup>2</sup> infection;
- 6) persons who have been exposed within the preceding 12 months to known or suspected HIV, HBV, and/or HCV infected blood through percutaneous inoculation (e.g., needlestick) or through contact with an open wound, non-intact skin, or mucous membrane;
- 7) children born to mothers known to be infected with, or at risk for, HIV, HBV or HCV infection, who are 18 months of age or less and/or have been breastfed within the preceding 12 months, regardless of the child's (*donor's*) HIV, HBV or HCV status;  
  
NOTE: Children over 18 months of age born to mothers infected with, or at risk for, HIV, HBV or HCV infection, who have not been breastfed within the preceding 12 months and whose infectious disease testing, *physical examination/physical assessment*, and review of medical records do not indicate evidence of HIV, HBV or HCV infection, *may* be accepted as *donors*.
- 8) persons who have been in a juvenile correctional facility, lockup, jail or prison for more than 72 consecutive hours in the preceding 12 months;
- 9) persons with a generic history of hepatitis of an unspecified etiology or a current or past diagnosis of clinical, symptomatic viral hepatitis unless evidence from the time of illness documents that the hepatitis was diagnosed as either hepatitis A or due to cytomegalovirus or Epstein-Barr virus hepatitis. (Note: A verbal history of viral hepatitis occurring before the age of 11 years is acceptable);
- 10) persons who have lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C<sup>2</sup> infection in the preceding 12 months;
- 11) persons who had or have been treated for syphilis or gonorrhea during the preceding 12 months. *Donors may* be acceptable if evidence is presented that the treatment occurred more than 12 months ago and was successful;
- 12) persons who within 12 months prior to donation have undergone tattooing, acupuncture, ear or body piercing in which shared instruments are known to have been used;

- 13) persons with a diagnosis of any form of Creutzfeldt-Jakob disease (CJD) or known family history (blood relative) of a person with non-iatrogenic CJD;
- 14) persons with a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology. Note: Tissues from donors with dementia, confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of transmissible spongiform encephalopathy (TSE) on microscopic examination of the brain, *may* be acceptable based on an evaluation of this information by the Medical Director;
- 15) persons who have received injections of human pituitary-derived growth hormone (pit-hGH);
- 16) persons who are known to have received transplants of human *dura mater*;
- 17) persons with encephalitis or meningitis of viral or unknown etiology that is active;
- 18) persons who have received transfusions of blood or blood products outside of the United States (U.S.) during specific time periods in the following countries:
  - a) from 1980 to present: France or the United Kingdom (includes England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands); and/or
  - b) after 1977 to present: Central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria)<sup>3</sup>.
- 19) persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:
  - a) spent three months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996;
  - b) lived cumulatively for 5 years or more in Europe<sup>4</sup> from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996); and/or
  - c) is a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996;
- 20) persons who, within the previous 120 days, have been told by a healthcare professional that they were suspected or known to have had a West Nile virus (WNV) infection based on symptoms, and/or those who are known to have tested positive for WNV by a NAT assay within this time frame;
- 21) persons who are known to have risks associated with xenotransplantation<sup>5</sup> (i.e., receipt of a xenotransplantation product<sup>6</sup> or who has had intimate contact<sup>7</sup> with a recipient of a xenotransplantation product);
- 22) persons who have been permanently deferred as a blood donor for unknown reasons or who have a history of positive infectious disease test results for HIV, HBV, or HCV;
- 23) persons who, within the past six months, were bitten by an animal suspected to be infected with



rabies. Individuals with suspected rabies *shall* not be accepted as *donors* under any circumstances (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

- 24) persons who had known or suspected sepsis at the time of death, or at the time of donation in the case of a *living donor*;
- 25) persons who, since 1977, were born in or have lived in any area of central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, and Nigeria) and persons known to have had sexual contact with any such person<sup>3</sup>;
- 26) persons who have had a recent smallpox vaccination (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact<sup>8</sup> with someone who received the smallpox vaccine;
- 27) persons whose cause of death (COD) cannot be determined and there is likelihood of other exclusionary criteria;
- 28) persons who are known to have malaria or be at risk for malaria; ~~and~~
- 29) reproductive donors who have had or have been treated for *Chlamydia trachomatis* or *Neisseria gonorrhea* infection in the preceding 12 months. If infection and treatment occurred more than 12 months ago, evidence of successful treatment such as a negative test result *must* be documented.
- 30) living donors who received a blood transfusion within the preceding 12 months unless approved by the Medical Director in conformance with generally accepted standards of practice (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);
- 31) birth tissue donated at vaginal delivery when there is significant local viral, parasitic, mycotic, or bacterial infection of the birth canal and, for any delivery, a current intrauterine infection;
- 32) persons with a history of being diagnosed with Ebola virus disease or who are at risk based on current CDC risk information; and
- 33) based on current recommendation published in FDA guidance, persons who have been determined to be at risk for infection with Zika virus.

<sup>1</sup>RELEVANT COMMUNICABLE DISEASE AGENT OR DISEASE (RCDAD) - A potentially infectious *microorganism*, virus, or other disease agent that may pose a risk of transmission to *recipients* of, or those who come in contact with, *tissues*. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential *donor* population; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for *donor* specimens has been cleared, approved, or *FDA*-licensed, and is available. There can also be those disease agents or diseases that could place potential *donors* and/or *recipients* at risk for infection due to accidental or intentional release. RCDADs applicable to all ~~cell and/or tissue donors~~ are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, WNV, vaccinia, and sepsis. Donors of viable, leukocyte-rich *tissues* must additionally consider HTLV I/II, and *donors of reproductive tissues* must generally consider *Chlamydia trachomatis* and *Neisseria gonorrhea*.

<sup>2</sup>CLINICALLY ACTIVE HEPATITIS C - Infection with hepatitis C virus when it is symptomatic. This means that: the person demonstrates related symptoms such as jaundice, icterus, fatigue, abdominal pain, loss of appetite, nausea, vomiting, diarrhea, low grade fever, headache, joint pain, and/or “flu-like

symptoms” **AND**, HCV infection is suspected or has been diagnosed or anti-HCV (EIA) testing is positive. Also, knowledge of a recent/current positive test for HCV NAT would qualify as a clinically active HCV infection.

<sup>3</sup>*Tissue banks* using an HIV test that has been approved by *FDA* to include a *donor* screening claim for detection of HIV Group O antibodies are not required to screen for this risk history.

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

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

<sup>6</sup>XENOTRANSPLANTATION PRODUCT - [Live](#) cells, tissues, or organs used in xenotransplantation. Biological products, drugs, or medical devices sourced from nonliving cells, tissues, or organs from nonhuman animals, including but not limited to porcine insulin and porcine heart valves, are not considered xenotransplantation products.

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

<sup>8</sup>CLOSE CONTACT: SMALLPOX - Physical contact with the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an unbandaged vaccination site.

#### Sources:

U.S. Department of Health and Human Services, Food and Drug Administration, Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule (69 FR 29785, May 25, 2004).

U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS) dated August 8, 2007.

~~U.S. Department of Health and Human Services, Food and Drug Administration, Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria dated June 2000.~~

[U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria dated August 2013. Updated August 2014.](#)

[Title 10 \(Health\) New York Codes, Rules and Regulations, Part 52. February 24, 2007](#)

## **Appendix III: TISSUE DONOR PHYSICAL ASSESSMENT FORM REQUIREMENTS**

### **Introduction**

This new appendix was derived from a document formerly titled “AATB Guidance Document No 1, v2 Tissue Donor Physical Assessment Form, 6-27-05.” As an appendix, compliance is mandatory. The form and instructions that follow *must* be used to document the *tissue donor physical assessment*.

There are specific requirements related to *tissue donor* identification and *physical assessment*. Standard D4.120 requires that, “Prior to the *recovery* of *tissue* from a deceased *donor*, a *physical assessment* shall be performed by a *responsible person*.” This standard also lists physical findings that may be an indication of infection with, or high risk behavior for, HIV or viral hepatitis, observations that may alert *recovery* personnel to signs related to an active infection (communicable disease) or to contamination due to trauma or medical intervention, all of which can affect *donor* eligibility. Other standards related to significant steps of this process are found in Section C and parts of Section D and Section F such as: *authorization*, *relevant medical records* review, autopsy report, *donor* identification *verification procedures*, and disease screening for infections and conditions that include risk factors and malignancies. These standards cover and exceed expectations in relevant FDA guidance [1].

In 2004, to completely and properly document the *physical assessment* of a *donor*, the AATB membership developed a “Tissue Donor Physical Assessment Form” and a corresponding “Standard Operating Procedure (SOP)”. The original version was a guidance document and it was updated once. Version 2 was issued in 2005 after a work group, comprised mostly of the members who created the original version, suggested improvements to the form after it was in use for about a year.

Six years later, new volunteers headed by the officers of the Recovery and Donor Suitability (RADS) Council, began to meet by conference call and online meetings to modernize the form and the instructions. Their expertise provided many improvements and added a page to the form. Review opportunities were provided to the Quality Council, the Processing and Distribution Council, all members of the RADS Council, as well as to the Physicians’ Council, and their comments were deliberated before sending final recommendations to the Standards Committee. The Standards Committee reviewed the updates and sent the recommendations to the Board of Governors who approved it as a new appendix to the *Standards*.

*Tissue banks* can adapt and personalize forms and *SOPs* for use in either paper or electronic format, however, all of the contents of this form *must* be included in any format used. *Tissue donor physical assessment* is a significant step in the *donor* eligibility process therefore staff training and periodic evaluation of *competency* is expected. Electronic documentation systems *shall* meet the same requirements for compliance as paper documentation *records*. Uploads (e.g., photos, documents, etc.) can occur during certain steps of the documentation expectations for *physical assessment*. The size of the body schematic is important to optimize documentation; the size of the schematic *must* not be reduced to the point that a reviewer is unable to distinguish the many notations that can be made.

### **Instructions**

The purpose of these instructions is to describe how to properly complete the three-page AATB Tissue Donor Physical Assessment Form. The information contained on these pages and in *relevant medical records* will be used as an aid to determine *donor* eligibility in order to proceed with *tissue recovery*.

This form *shall* be completed in its entirety, prior to *recovery* of *tissues*. Internal findings *should* also be documented in *tissue recovery records* but, except for documenting whether lymph nodes appear

abnormal, this aspect is not addressed here. An “internal findings form” may be developed separately.

This *record* identifies the staff involved in each significant step of the *physical assessment procedure*, and documents: *donor* identification and *authorization verification procedures*; the *donor's* appearance and evidence of donation of organs and/or ocular tissues; the status of an autopsy (if any); a description of each finding; whether photos were taken and if consultations occurred; if there were personal effects and their disposition; and, a summary that attests to acceptability to proceed with *recovery*.

## Abbreviations

The following abbreviations are used:

- e.g. - *exempli gratia*; for example, such as; the list is not finite
- i.e. - *id est*; that is; indicates a finite list
- ft - feet
- cm - centimeters
- in - inches
- kgs - kilograms
- lbs - pounds
- ET - endotracheal
- ID - identification
- IV - intravenous
- N/A - not applicable
- NG - nasogastric
- Ortho – orthopedic
- UNOS - United Network for Organ Sharing

## Materials

- Indelible ink (blue or black);
- AATB Tissue Donor Physical Assessment Form or fully compliant version (paper or electronic substitute); and
- *Relevant medical records*, including but not limited to: the *document of gift* or *document of authorization*, the *donor risk assessment interview* form, and available, *relevant medical records*.

## Safety

Follow established blood borne pathogen precautions.

## Instructions for Completing Page 1

Completion of this page: 1) describes how the *donor* was identified; 2) describes the *donor's* appearance and documents evidence of previous donation of ocular tissues and/or organs; 3) describes the status of an autopsy; 4) documents the *recovery* team's *physical assessment* findings using a required list of potential risk factors; and, 5) identifies personnel who *verify donor* identification. Information may be derived from available *relevant medical records*, source documents, and/or personnel involved with the care of the patient/*donor*.

Step	Action
<b>Identification</b>	
1	Document the complete name of the <i>donor</i> as written on the <i>document of gift/authorization</i> .
2	Document the recovery agency's unique <i>donor</i> ID.
3	The manner in which the <i>donor</i> was identified is documented by checking the box next to the

	applicable word(s): “ID Band,” “Body/Toe Tag,” or “Other.” If “Other” is selected, it <i>must</i> be described. Multiple identifiers <i>may</i> be checked.
4	Recreate the ID Band/Tag containing the most information. All identifying tags/bands <i>should</i> match. Or check N/A ID not present if there is no ID band/tag present, or check N/A Photo taken/saved if a photo of the ID Band/Tag was taken/saved instead.
5	Check the “Yes” or “No” box to indicate if there is agreement among <i>recovery</i> team personnel that the body’s physical characteristics (e.g., age, gender, race, height, weight, signs associated with the cause of death, or information on the <i>DRAI</i> form) are consistent with available <i>relevant medical records</i> and the identification is consistent with other documents. If “No,” appropriate management <i>shall</i> be contacted for guidance before proceeding with <i>recovery</i> . The <i>SOPM</i> <i>shall</i> include directions when the <i>donor’s</i> identification is discrepant or questionable.
6	On the line provided, print the names or initials of the <i>tissue recovery</i> personnel present that <i>verified</i> the <i>donor’s</i> identification. Document the date and time noting when this step was completed. Identify the appropriate time zone per <i>SOPM</i> .
<b>Appearance/Evidence of Donation</b>	
7	Enter a number for the height of the <i>donor</i> followed by checking a box indicating the appropriate selection designating whether this is inches (in.) or centimeters (cm.).
8	Check the box that indicates the method the team used to obtain the height: use “estimated/team” if estimation by the team's <i>responsible person(s)</i> ; use “actual” if direct measurement was performed; use “reported” if <i>relevant medical records</i> (for “source”, enter the specific source). The <i>responsible person(s)</i> of the team <i>must</i> agree upon and document one value for height. Check multiple boxes if the team used multiple methods.
9	Enter a number for the weight of the <i>donor</i> . Check the box for units used [pounds (lbs) or kilograms (kgs)].
10	Check the box that indicates the method the team used to obtain the <i>donor’s</i> weight: use “estimated/team” if estimation by the team’s <i>responsible person(s)</i> ; use “actual” if direct weighing; use “reported” if relevant medical records (for “source”, enter the specific source). The <i>responsible person(s)</i> of the team <i>must</i> agree upon and document one value for weight. Check multiple boxes if the team used multiple methods.
11	Upon initial body assessment, check the box to describe the state in which the body was found such as: evidence of decomposition (e.g., skin sloughing, putrefaction); or, “cleanliness” (e.g., presence on the body of broken glass, dirt, leaves, grime, road abrasions). If “Poor”, describe condition.
12	Check “No” or “Yes” to document evidence of ocular donation. If “Yes”, then check either “corneas only” or “whole eyes” as appropriate.
13	Check “No” or “Yes” to document evidence of organ donation. If “Yes”, then enter the UNOS #.
<b>Autopsy Status</b>	
14	Check appropriate box to indicate if <i>tissue recovery</i> is “pre” or “post” autopsy, if no autopsy is planned, or, if the autopsy plan is unknown.
15	If an autopsy has been done or is planned, indicate the appropriate type describing it as “full”, “limited (e.g., head only),” “view only,” “toxicology screen only,” or if the plan for autopsy is “unknown.” Check only one. Intent can be met if knowledge of the autopsy plan is documented on a form other than the Tissue Donor Physical Assessment Form, however, the information included on the Tissue Donor Physical Assessment Form <i>must</i> be covered in entirety (i.e., all the options listed <i>must</i> be covered). In cases where some <i>tissue</i> is <i>recovered</i> pre-autopsy (e.g., ocular) and more tissue (e.g., bone) is recovered post-autopsy, the events <i>should</i> be documented in the <i>donor record</i> and reflected on the schematic."

<b>Assessment</b>	
16	For each step #17 through # 28 inclusive, check “No” or “Yes”. If “Yes”, then describe the finding thoroughly. If visualization or palpation is not possible, then check the box and explain why.
17	Are abnormal ocular findings (e.g., icterus, scarring) present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”). If ocular tissue was <i>recovered</i> prior to this assessment, then check “Unable to visualize” and follow-up with personnel at the local Eye Bank to obtain document.
18	Are white or yellow spots in the mouth present? Check “No” or “Yes”. If “Yes”, then describe. Check “Unable to visualize” if oral cavity is not accessible to visualize and explain why. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
19	Is jaundice present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
20	Are signs of trauma or infection present on the body where <i>recovery</i> of <i>tissue</i> is planned ( <i>tissue recovery</i> areas)? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
21	Is a rash, scab, or non-genital <i>skin</i> lesion present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
22	Are blue/purple (gray/black) spots/lesions present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
23	Are signs of non-medical injections present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
24	Document if no enlarged lymph/abnormal node(s) is (are) observed (“No”), or if any are observed (“Yes”). Explain any “Yes” findings here or, if space is limited, document where the description can be found (e.g., see schematic, see Notes, etc.). Lymph nodes can be palpated bilaterally just under the <i>skin</i> of the neck, axilla, and groin. When lymph nodes can be visualized and are found to be enlarged/abnormal, such findings <i>must</i> be documented in the <i>recovery records</i> however there is not an expectation to identify them on the body schematic. An enlarged lymph node can appear swollen [a node that is an inch (2.5 centimeters) or more in diameter in an adult], and abnormal findings can be if it is draining pus or feels hard [2].
25	Is evidence of an enlarged liver (hepatomegaly) present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”). If the liver cannot be assessed, then check “Unable to assess” and explain. If liver is not present, there is an expectation to follow-up to obtain documentation of the description of the liver (e.g., with OPO personnel, a pathologist, a researcher).
26	Are genital lesions present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
27	Are perianal lesions or anal trauma present upon rectal examination? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
28	Are tattoos/piercing present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).

### Instructions for Completing Page 2 (Schematic)

Completion of this page documents all of the *physical assessment* findings by team members by recording them on anterior and posterior body diagrams (schematics) using a standardized Key. This will include

those findings documented during assessment on page 1 plus any other observations. Documentation also occurs if no findings are seen on either schematic view. Personnel who perform the *physical assessment* are identified as well as when it was performed.

1	Document the recovery agency's unique <i>donor</i> ID.
2	All gross findings are appropriately drawn or otherwise identified (i.e., such as when using electronic <i>records</i> ) on the anterior and posterior body schematics using the lettered Key provided. Blank schematic Key spaces are available to document gross findings not listed and/or to provide areas to further describe any listing [e.g., (H), (N)]. Piercing location, body jewelry, and each tattoo's location and content are important to describe on this form or in additional notes.
3	If no findings are evident on either schematic view, check the appropriate box below it to indicate "no observations noted."
4	Document the name or initials of each team member who performed the <i>physical assessment</i> . Document the date and time noting when this step was performed. Identify the appropriate time zone per <i>SOPM</i> .

### Instructions for Completing Page 3 (Summary)

Completion of this page documents: 1) if any photos of the body were taken; 2) if consultation occurred regarding *physical assessment* findings; 3) if personal effects were with the body and if so a description of which ones and their disposition; and, 4) a summary and whether this *donor* is acceptable or not to proceed with *tissue recovery*.

1	Document the recovery agency's unique <i>donor</i> ID.
2	Were photos of the body taken? Check "No" or "Yes". If "Yes", then provide relevant information about the photos in the "Notes" section. A process <i>should</i> be established to share photos upon request from the <i>tissue bank</i> determining donor eligibility. This question regarding taking of photos <i>must</i> be addressed but intent is met if this information is captured on a form other than the Tissue Donor Physical Assessment Form.
3	Did consultation of <i>physical assessment</i> findings occur? Check "No" or "Yes". If "Yes", then provide relevant information about any consultation in the "Notes" section. This area can also be used for documenting details regarding whether a biopsy was requested and taken.
4	Document if there are no personal effects with the <i>donor</i> body ("No") or check "Yes" if personal effects are present. Personal effects can be, for example, clothing, a wallet/purse, cash, credit cards, drug paraphernalia, mobile phone, and/or jewelry but, if present, require a description and their disposition. Intent is met if personal effect information is documented on a form other than the Tissue Donor Physical Assessment Form.
5	After a review of available <i>relevant medical records</i> and the <i>physical assessment</i> findings have been completed, a <i>responsible person</i> from the <i>recovery</i> team must indicate "acceptable" or "not acceptable," then document their name or initials and date of completion of this process. Identify the appropriate time zone per <i>SOPM</i> .
6	After all documentation has been reviewed for legibility, completeness and accuracy, the form is appropriately forwarded.

### Notes Regarding Documentation

Standard C1.100 requires that "Documentation must be made concurrent with each significant step." All findings *must* be documented concurrently with the performance of the physical assessment. Any changes made to the document after the examination *must* include the date the change was made, initials of the person making the change, and the reason/rationale for the change. Changes to actual findings *should* be



based on photos that support the change.

The spaces provided on this form for documenting observations *may* be expanded to meet local policy, such as adding a listing for “lividity” or “rigidity/contractures” in the Key, adding space reserved for documenting more notes, or increasing the space for documenting names, numbers, or identifiers. Other additions *may* be made but the content of this form *must* be included in entirety. For example, the letter selected to identify any listing in the Key can be different but all of the listings in the Key to this guidance document *must* be used. The size of the body schematic is important to optimize documentation; the size of the schematic *must* not be reduced to the point that a reviewer is unable to distinguish the many notations that can be made.

Proper methods of documentation *must* be utilized, including revisions to *records*. Revisions *shall* be made with a single line drawn through the altered text with the revision initialed and dated by the person making the revision. Additions to a completed *record shall* be initialed and dated by the individual making the additions (see C1.500). All entries *must* be legible.

It’s preferred that documentation concerning “time” be based on a 24-hour clock (military time). Use of the notations “pm” and “am” is not preferred. *Tissue recovery* documentation *shall* use the time zone appropriate to the time and place of *recovery*.

*Deviations* from written *procedures shall* be documented and shared with all entities that determine *donor* eligibility and approve release of *tissue*.

## References

1. U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), August 8, 2007.
2. The Merck Manual, Home Health Handbook for Patients and Caregivers, [http://www.merckmanuals.com/home/heart\\_and\\_blood\\_vessel\\_disorders/lymphatic\\_disorders/swollen\\_lymph\\_nodes.html](http://www.merckmanuals.com/home/heart_and_blood_vessel_disorders/lymphatic_disorders/swollen_lymph_nodes.html) (accessed April 30, 2016)

## Historical Changes

Previous Page #	Summary of Changes
New on 2/23/04 (SAB/AM/AG)	
Version 2 effective date 6/27/05 (PA Workgroup/SAB)	
1	Added reference to this being “Version 2”, new date, and address updated
3	Table of Contents pages and titles updated
4	Provided listing of standards that are related; verbiage changes and additions made for clarification; reference to staff training and competency added.
5	Updates made to abbreviations in B.; addition of “available, relevant” to medical records; and punctuation changed in part E.
6	Verbiage additions and changes made for clarification.
7	Verbiage additions and changes made for clarification. “Globes” replaced with “whole eyes” to match EBAA terminology.
8	Removed “icterus” in step 17 and placed it in later step (28); adjusted wording accordingly.
8	Step 19 amended to document the new observation listing for “tattoos/piercings” to

	accommodate new federal guidance (Donor Eligibility).
8	Removed instruction in step (old 22) that is no longer considered part of <i>physical assessment</i> : “Document by checking the appropriate box, if infectious precautions are known for this patient (“Yes”), or not (“No”).”
8	Changed “perianal warts” to “perianal lesions” to encompass more possibilities that may be seen.
8	Added provision for documenting evidence of rash, scab, or skin lesion (non-genital) to accommodate new federal guidance (Donor Eligibility).
9	Change to step 28 is to address documentation of abnormal ocular findings that was added to accommodate new federal guidance (Donor Eligibility).
9	Documenting limitations of visualization when it’s restricted is offered as needed.
9	Body Appearance section amended to report “Cleanliness” instead of “Basic Hygiene” to accurately reflect intent; and, “Body Profile” deleted since height and weight is previously reported.
9	Step numbers updated and order of last two steps changed.
10	In step 2, use of blank schematic Key spaces is now described.
10	Ampersand (&) included in deletion example.
10	Part G. amended to include general instruction to document/share any deviations from written procedures that occur.
13	Identification area updated by: 1) adding “/gender” to “sex”; 2) adding checkbox for height measurement in centimeters; 3) addition of “source:” and lines for documenting it for both “reported” height and weight assessments. “Actual” assessment box for height and weight moved to last selection in the row since it likely occurs less often than others. Changed case for capitalizations of measurements.
13	Evidence of Donation/ Autopsy area changed to list “whole eyes” instead of “globes”.
13	Recovery Team Assessment area updated by: 1) removal of icterus from first checklist item, then added later in listing for ocular findings; 2) addition of individual checklist item for “tattoo/piercing”; 3) addition of individual checklist item for “rash, scab, skin lesion (non-genital)”; 4) additional individual checklist item for “abnormal ocular finding (i.e. icterus, scarring)” with further checkbox provision for “unable to visualize”, if applicable; 5) limitation for visualization of “oral cavity” removed since there are two scenarios that can occur now. Added “Notes/” to “Explain if unable to visualize...” to clarify intent to document anything relevant in space provided.
13	In the General Appearance area, deleted “Basic Hygiene” and changed to “Cleanliness”; entirely deleted Body Profile and selections.
13	Switched order of last two line items.
14	Added a selection for labeling a ‘scab’ by using the letter W. Changed “for” to “prior to” in Summary.
15, 16	Added example pages of the sample form completed in entirety for a fictitious donor.
13–16	Removed all checkboxes and spaced selections appropriately.
6–8	Changed all references to “checking” or “box” and replaced them with directions to circle appropriate selection or word.
Appendix III (RADS Council Workgroup/SAB)	
1	The title was changed from a guidance document to an appendix. This was done to clarify original intent that using this form and following the instructions are mandatory.
3	The list of latest contributors was added.
4	Section listings have been expanded with new subsections; pages and titles updated.
5	The Introduction was expanded to include: a broader description of other standards related to significant steps of the <i>donor</i> eligibility determination process; a description that this method, or an equivalent method, <i>shall</i> be implemented, and that periodic evaluation of

	competency is expected for staff performing <i>physical assessment</i> ; clarification that electronic documentation systems <i>shall</i> meet the same requirements for compliance as paper documentation records; and, a description of this version's development and the approval process.
6, 7	The Purpose is described in more detail, more Definitions and Abbreviations were added, and the Materials section updated to clarify that full compliance is expected. It is additionally described that, except for documenting whether lymph nodes appear enlarged/abnormal, this guidance document does not address internal findings and that an "internal findings form" can be developed separately.
8 to 11	On each page, the procedural steps were updated to align with changes to the form in regard to: the new order of the listing of signs in the Assessment box; the switched order of documenting "No" and "Yes" which are now further separated on the form to provide better documentation practice; and, descriptions changed to documenting "No" or "Yes" instead of using directions to "circle appropriate selection or word."
8	In the Identification box, procedural steps have been revised to meet changes to the form such as: documentation of agreement among <i>recovery</i> team personnel that the body's physical characteristics and identification are consistent with available <i>relevant medical records</i> ; direction provided to contact appropriate management for guidance prior to <i>recovery</i> if there is a discrepancy regarding identification of the body; the procedure describes an expectation that the SOPM shall include directions when the donor's identification is discrepant or questionable; and, there was an addition made to document not only the date and time when these critical steps were performed but also the appropriate time zone.
9	Procedural steps were updated to describe more detail how the donor's weight was derived and that the weight documented was agreeable to all recovery personnel, and a new selection was added to the type of autopsy (i.e., toxicology screen only).
10	Procedural steps were updated to describe more detail, especially: when there is an expectation to contact the local Eye Bank and obtain documentation of their ocular assessment; the possible color of spots in the mouth was expanded to include not only white but also yellow; the locations on the body where lymph nodes can be palpated were added; findings of abnormal lymph nodes <i>must</i> be documented but there is not an expectation to identify them on the body schematic; a description was added to provide background on the size of an enlarged lymph node and that abnormal findings can relate to draining pus and/or if it feels hard; and, a reference to the Merck Manual was added. For a few listings that have multiple terms in a listing, a new description states there is no longer an expectation to also circle the word(s) in the listing to indicate which finding(s) were identified, but it (they) <i>must</i> be clearly explained and identified on the schematic.
11	Procedural steps were updated to describe more detail, especially: to allow documentation when the liver cannot be palpated and space to explain why; that there is an expectation to document if a tattoo is suspected to be recent/new and descriptive examples are now provided (i.e., scabbing is present on tattoo, tattoo area is shaved, tattoo has vibrant colors, or if there is inflammation/swelling/redness within the tattoo), and that providing a description (location and content/subject) of any tattoos and the location of piercings and type of body jewelry are also expectations; and, the observation for "perianal lesions or insertion trauma" was changed to "perianal lesions or anal trauma" because referencing "insertion trauma" could be subjective. At "Instructions for Completing Page 2 (Schematic)" it now states that a standardized Key is used, and that documentation also occurs if there are no findings on either schematic view. A summary was added that completion of a new page expects the following additional documentation: 1) if any photos of the body were taken; 2) if consultation occurred regarding <i>physical assessment</i> findings; and 3) if personal effects were with the body. Direction includes that any consultation be explained in the "Notes" section, and that this area can also be used for documenting details

	regarding whether a biopsy was requested and taken. If personal effects are present a description and their disposition is now required documentation.
12	A new section (Notes Regarding Documentation) gives a description that spaces provided on this form for documenting observations can be expanded to meet local policy and that additions can be made to the form but the content of this form <i>must</i> be included in entirety. It's now clarified that documentation concerning "time" is preferable when based on a 24-hour clock (military time). Use of the notations "pm" and "am" are now described as not preferred. Documenting the appropriate time zone for the respective region has been added. Documenting and sharing deviations is now required when the deviation can affect the eligibility determination of the donor or release of tissue. The list of references was updated and a few added. The section on Historical Changes was reformatted.
13	A comment period produced a number of recommendations that were accepted in full, accepted in part, or rejected. Refer to "Compiled Comments & Responses to Tissue Donor Physical Assessment Form".

The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to creating these requirements.

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# AATB Tissue Donor Physical Assessment Form

## Identification:

Name on Document of Gift/Authorization: \_\_\_\_\_ Recovery Agency ID: \_\_\_\_\_

Manner identified by: ☐ ID Band ☐ Body/Toe Tag ☐ Other (describe): \_\_\_\_\_

## Identification Band/Tag:

ID re-created:

Or:

- ☐ N/A Photo taken/saved  
☐ N/A ID not present

The body's physical characteristics (e.g., age, gender, race, height, weight, signs associated with the cause of death, or information on the DRAI form) are consistent with available relevant medical records, and the identification is consistent with other documents.

☐ Yes ☐ No

If answered "NO," contact appropriate management for guidance before proceeding with recovery.

**Personnel verifying donor ID:** \_\_\_\_\_ **Date/Time/Zone:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## General Appearance/Evidence of Donation:

Height: \_\_\_\_\_ ☐ in ☐ cm **Height is:** ☐ estimated/team ☐ actual ☐ reported (source : \_\_\_\_\_)

Weight: \_\_\_\_\_ ☐ lbs ☐ kgs **Weight is:** ☐ estimated/team ☐ actual ☐ reported (source : \_\_\_\_\_)

**Cleanliness:** ☐ Good ☐ Poor (Describe if poor): \_\_\_\_\_

Ocular Donation: ☐ No ☐ Yes If "Yes," ☐ corneas only ☐ whole eyes

Organ Donation: ☐ No ☐ Yes If "Yes," UNOS # \_\_\_\_\_

**Autopsy Status:** ☐ Pre-Autopsy Recovery ☐ Post-Autopsy Recovery ☐ No Autopsy Planned ☐ Unknown

**Type:** ☐ Full ☐ Limited ☐ View only ☐ Toxicology screen only ☐ Unknown

## Assessment:

**Are there signs of any of the following? Explain "Yes" answers, or any if "unable to visualize/palpate."**

☐ No....Abnormal ocular findings (e.g. icterus, scarring) ... ☐ Yes ☐ Unable to visualize: \_\_\_\_\_

☐ No....White/Yellow spots in the mouth ..... ☐ Yes ☐ Unable to visualize: \_\_\_\_\_

☐ No....Jaundice ..... ☐ Yes: \_\_\_\_\_

☐ No....Trauma/Infection to tissue recovery areas ..... ☐ Yes: \_\_\_\_\_

☐ No....Rash/Scab/Skin lesion (non-genital) ..... ☐ Yes: \_\_\_\_\_

☐ No....Blue/Purple (gray/black) spots/lesions ..... ☐ Yes: \_\_\_\_\_

☐ No....Non-medical injection site ..... ☐ Yes: \_\_\_\_\_

☐ No....Enlarged/Abnormal lymph node(s) ..... ☐ Yes: \_\_\_\_\_

☐ No....Enlarged liver ..... ☐ Yes ☐ Unable to assess: \_\_\_\_\_

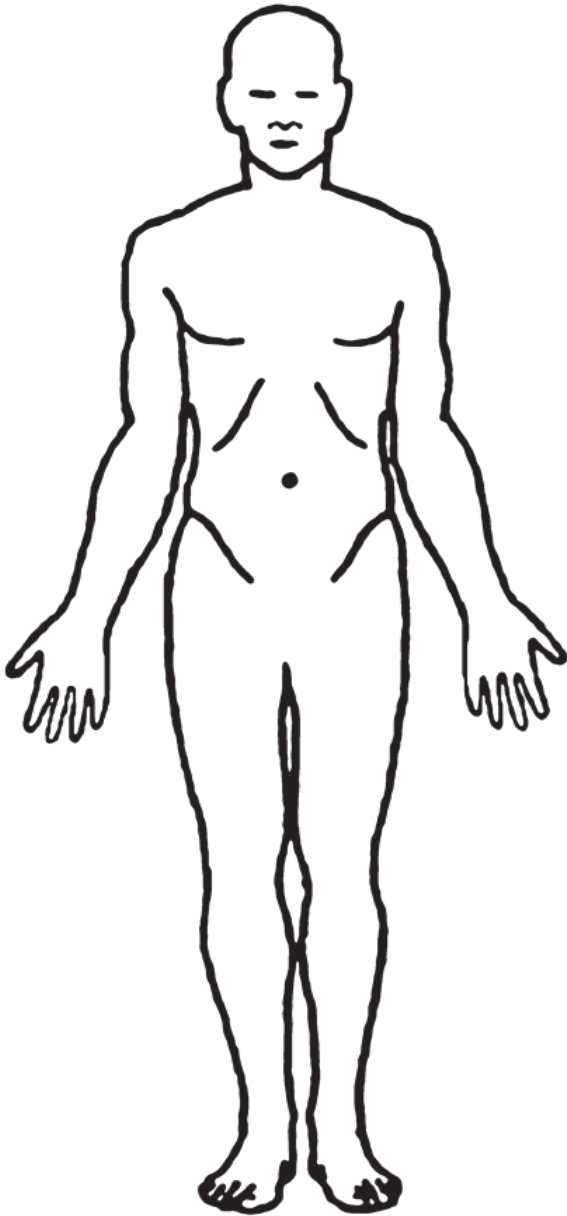
☐ No....Genital lesions ..... ☐ Yes: \_\_\_\_\_

☐ No....Perianal lesions or Anal trauma ..... ☐ Yes: \_\_\_\_\_

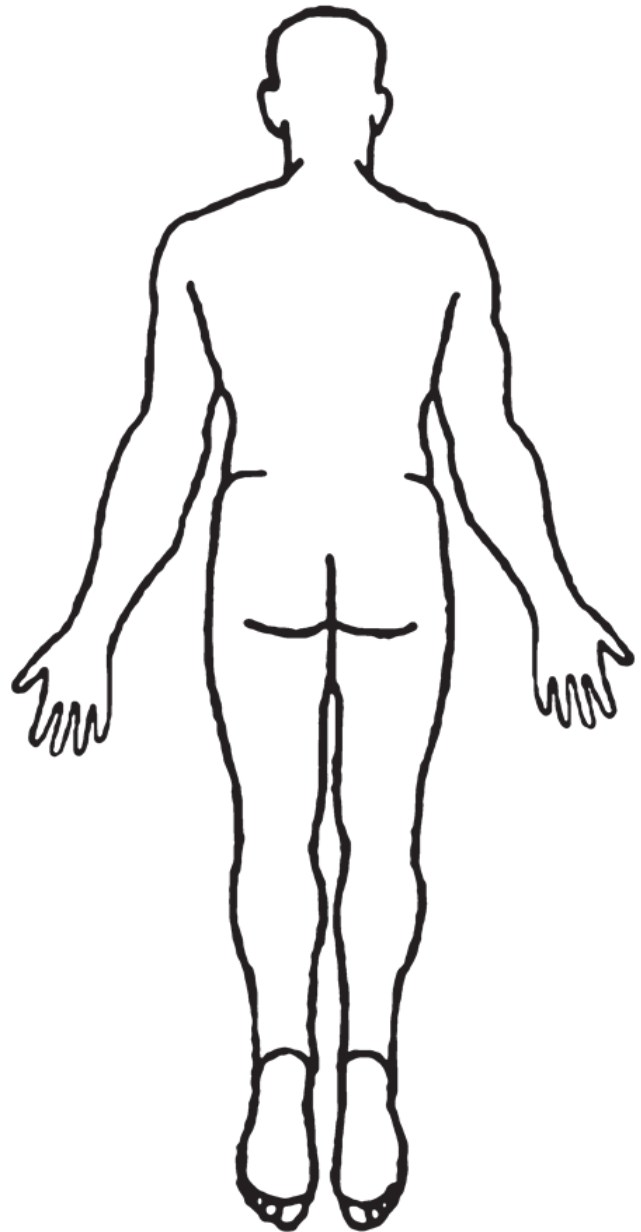
☐ No....Tattoos/piercing ..... ☐ Yes: \_\_\_\_\_

# Tissue Donor Physical Assessment Schematic

Recovery Agency ID: \_\_\_\_\_



☐ Check if no observations noted



☐ Check if no observations noted

## Key to Schematic:

(A) Abrasion	(N) Body piercing – requires description
(B) Bruise/Contusion/Hematoma	(O) Urethral catheter
(C) Cast/Ortho device	(P) Skin lesion – requires description
(D) Dressing/Bandage	(Q) Scar (surgical/trauma)
(E) ET tube/NG tube	(R) Rash
(F) Fracture/Dislocation	(S) Ocular Donation
(G) IV/IO/Arterial Line	(T) Tattoo – requires description (also note if suspected to be new)
(H) Skin Tag(s)	(U) Stretch mark(s)
(I) ID Band/ Tag	(V) Mole
(J) Laceration/Wound	(W) Team Blood Draw Site
(K) Autopsy Incision	(X) _____
(L) Needle entry site	(Y) _____
(M) Organ Recovery Incision	(Z) _____
	(AA) _____

Physical Assessment performed by: \_\_\_\_\_ Date/Time/Zone: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Tissue Donor Physical Assessment Summary

Recovery Agency ID #: \_\_\_\_\_

☐ No..... Were photos of the body taken?..... ☐ Yes

☐ No..... Did consultation of physical assessment findings occur? ... ☐ Yes

Notes:

☐ No..... Personal effects with body..... ☐ Yes

If yes, check only those that apply and describe:

☐ Clothing ..... Describe: \_\_\_\_\_

☐ Wallet/purse..... Describe: \_\_\_\_\_

☐ Jewelry ..... Describe: \_\_\_\_\_

☐ Other ..... Describe: \_\_\_\_\_

☐ Other ..... Describe: \_\_\_\_\_

☐ Other ..... Describe: \_\_\_\_\_

☐ Other ..... Describe: \_\_\_\_\_

Disposition:

### Summary:

A review of available relevant medical records and physical assessment findings were completed prior to recovery and found to be: ☐ **acceptable.** ☐ **not acceptable.**

\_\_\_\_\_  
Responsible Person

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date/Time/Zone



**Appendix IV:**  
**PREVENTION OF CONTAMINATION AND CROSS-CONTAMINATION AT RECOVERY:**  
**PRACTICES AND CULTURE RESULTS REQUIREMENTS**

**Introduction**

In the spring of 2002, the Board of Governors assembled a Task Force to review reports of recipient infections that were allegedly associated with *tissue allografts*. In 2003, the Task Force made several recommendations that were considered by the Standards Committee. It was determined that additional steps could be taken to control the possibility of contamination and/or *cross-contamination* during *recovery* of *tissue* from deceased *donors*, and that the presence of certain *microorganisms* would necessitate discard of the *tissue*. The Committee also agreed that the interpretation of associated *recovery* (pre-processing) cultures from the same *donor* warrant scrutiny, and that sharing culture results is important.

The Board of Governors decided to include some of these recommendations in the AATB's *Standards for Tissue Banking*. Other recommendations were more representative of good practice, and these recommendations were published in the original version of this work when it was titled "Prevention of Contamination and Cross-contamination at Recovery: Practices & Culture Results, Guidance Document (No. 2), October 20, 2004."

In early 2006, a technical work group was formed to expand the content of the guidance to include another factor that could prevent contamination and *cross-contamination* at *recovery*. Suitability of the site where *tissue recovery* takes place *must* be evaluated and determined to be acceptable prior to *recovery*, and revisions were made to D5.500. The goal is to set specific guidelines/suitability parameters that define required controls. There is not an expectation that actual detailed monitoring be performed at each *recovery site*. Parameters have been developed that, when applied, can ensure that the environment in which *recovery* occurs meets minimum specifications and *should* not introduce, transmit, or spread contamination. These additional controls are appropriate and reasonable and have been formulated by this work group from practices tested and used by AATB-accredited *tissue banks*.

In January of 2007, another work group of subject matter experts was organized to collect information regarding how *tissue banks* were applying the *zone recovery* concept and *sequencing* to their *recovery* operations. These practices were reviewed for consistency and common practices were added to this work. There is consensus that documentation methods that describe zones and *sequencing* facilitate *tissue* suitability determinations. Version 2 of the guidance document was published on May 29, 2007 and included updates for *zone recovery* and *sequencing*, and added *recovery site* suitability parameters along with a sample form.

[In 2016, the guidance document became an appendix to the \*Standards\* when the 14<sup>th</sup> edition was published.](#)

**Definitions**

As used in this appendix, the following definitions apply:

**SEQUENCING** - A procedure utilized at *tissue recovery* that documents the order (sequence) that *tissues* were *recovered* from one *donor*.

**ZONE RECOVERY** - A *tissue recovery* method by which specific, well-defined areas of the body are identified as zones and from which individual *tissues* are *recovered* using the same

sterile instrumentation/equipment and sterile gloves. It is recommended that *skin recovery* be performed as a separate zone so that *pre-sterilization/pre-disinfection culture* results of other *tissues* can be independently reviewed.

**ISOLATION DRAPING** - A method used whereby areas adversely affected by trauma are first segregated (isolated) by entirely covering them to contain potential contamination and prevent *cross-contamination* to other *tissues recovered* from the same *donor*. If *tissues* from these areas are retrieved, they *should* be sequenced as the last to be recovered.

## Recovery Practices

### RECOVERY TECHNIQUES:

Certain *tissue recovery* practices may be helpful in controlling contamination and *cross-contamination* of individual *tissues*. These include *recovery* techniques such as *sequencing* of the *tissue recovery*, use of well-defined *zone recovery* techniques, and *isolation draping* in the presence of trauma (see D5.530). *Recovery* activities *should* be reviewed to help determine the likelihood of *cross-contamination* of individual *tissues*.

### RECOVERY SITE QUALIFICATION:

Parts of applicable federal regulations can be referenced (at §1271.190 Facilities, and at §1271.195 Environmental Controls and Monitoring) and used as guides for practical application when determining that a *recovery site* is satisfactory. The evaluation of the suitability of the site of *recovery must* be documented and this *record* shared with entities that receive *tissues* from the *donor* [at §1271.160 Quality Program, (b) Functions (2)]. Due to many circumstances related to events that could occur after death, the donor body may be moved to various sites (e.g., dedicated tissue recovery site, healthcare facility operating room, autopsy suite). The room in the building where *tissue recovery* takes place *must* offer a level of control that will not increase the potential to introduce contamination or cause *cross-contamination*. Minimum qualification parameters have been established that *should* ensure control of this environment and be *qualified for tissue recovery*.

Prior to *recovery*, the following evaluations are performed and there *must* be:

- 1) adequate floor and tabletop space to allow separation of sterile instrumentation and performance of *aseptic recovery procedures* (i.e., *zone recovery*, *sequencing*, *draping*, *tissue wrapping*);
- 2) adequate lighting to perform *physical assessment* and *tissue recovery*;
- 3) adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash;
- 4) a controlled, closed airflow system in the *recovery* area. This means there is no direct access to the outside of the building from the room at any time during, before, or after *tissue recovery* (e.g., doors, windows that can open, fans, air conditioners); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields;
- 5) walls, floor, and work surfaces that are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair;
- 6) no visible signs of insects, rodents, or other pests;

- 7) an evaluation for any standing fluids or contaminated waste in the room that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, and if present, it *must* be rectified prior to *recovery*; and
- 8) proper preparation of the *recovery site* by cleaning and *decontaminating* all working surfaces prior to *recovery of tissue*;

Concurrent with *tissue recovery*, the following site parameters *must* be controlled:

- 1) human traffic is restricted and all personnel entering the *recovery* area must be properly outfitted and their movement controlled; and
- 2) no other activities (i.e. embalming, autopsy, another *tissue donor recovery*) can occur simultaneously in the same room as this *tissue recovery*;

After *tissue recovery*, the following activities *must* be performed:

- 1) all contaminated/biohazardous re-usable supplies were *decontaminated*, and adequately contained for transport, and that contaminated/biohazardous waste was properly disposed, or contained and transported to a disposal site; and
- 2) all working surfaces and the floor were *decontaminated* using approved solutions and equipment.

Note: If there is an ability to rectify certain parameters that may not be initially met (e.g., there is a need to cover room furniture, drains, sinks, or walls), this *must* be described in *procedures*, and such a scenario warrants review by a designated, *responsible person* prior to proceeding with *recovery*. There *must* be assurance that there is no evidence that the scenario would compromise the suitability of the *recovery site* by being a source of contamination or *cross-contamination*.

*Recovery* personnel *must* document whether the above parameters have been met, and if the *recovery site* has been determined to be suitable. See “Sample Tissue Donor Recovery Site Assessment Form” in this appendix.

## ZONE RECOVERY AND SEQUENCING:

The primary objective of *zone recovery* is to reduce the potential spread of *microorganisms* (*cross-contamination*) from one region of the body to another by employing isolation techniques. Isolation is accomplished through evaluation of trauma, specific draping if necessary, placement of drapes after the *skin prep* has occurred, and by using dedicated instruments for each zone. The recovery technician *must* also make glove changes between zones and *may* change their gown when indicated (e.g., when it becomes soiled or contaminated, or when *sequencing recovery* from a zone that is at increased risk for contamination to a zone of lesser risk). By performing these functions and documenting actions this will facilitate suitability determinations made from *pre-sterilization/pre-disinfection culture* results. These guidelines are reproducible in multiple settings and scenarios and, when followed, can reduce the risk of contamination and *cross-contamination at recovery*.

A zone is identified as a region of the body. Zones are recovered in a sequence that is recorded, but the sequence order cannot be prescribed due to many possible variables. If preferred, gloves can be changed following each *tissue recovered* within a zone. In the presence of trauma when *isolation draping* methods are used, these areas become zones that are prepped and *tissue* excised only after *recovery* of all other *tissue* has occurred.

Some zones (i.e., *skin*, vertebrae/spine, the pelvis, thoracic cavity, traumatized areas) *should* be treated as inherently possessing an increased risk for contamination and warrant special consideration when *recovering tissue* in that zone (e.g., deciding the sequence of *zone recovery* and whether extra gown changes *should* occur). *Recovery records* *should* include space to document unanticipated zones due to trauma or other factors.

Common zones:

- *skin* - back, abdomen, left anterior leg, right anterior leg, left posterior leg, right posterior leg;
- ocular - corneas, sclera, whole globes;
- intracranial *tissue* - *dura mater*, brain;
- mandible;
- thoracic - heart, thoracic aorta, pericardium, ribs, nerves;
- abdomen - abdominal aorta, iliac artery and vein, nerves;
- upper extremity left - rotator cuff, humerus, radius, ulna, metacarpals, nerves;
- upper extremity right - rotator cuff, humerus, radius, ulna metacarpals, nerves;
- lower extremity right - vessels, assorted tendons, fascia lata, femur, tibia (with patellar ligament), tibia, fibula, Achilles tendon with calcaneus, talus, nerves;
- lower extremity left - vessels, assorted tendons, fascia lata, femur, tibia (with patellar ligament), tibia, fibula, Achilles tendon with calcaneus, talus, nerves;
- left hemi-pelvis/ilium - due to proximity of the hemi-pelvis to the viscera, these *tissues should* be *recovered* after all other *musculoskeletal tissues* from the respective extremity have been *recovered* and *packaged*;
- right hemi-pelvis/ilium - due to proximity of the hemi-pelvis to the viscera these *tissues should* be *recovered* after all other *musculoskeletal tissues* from the respective extremity have been *recovered* and *packaged*; and
- vertebrae/spine - cervical, thoracic, lumbar; due to the proximity of the vertebrae/spine to central nervous system fluids and *tissues*, these *tissues must* be considered a separate zone.

DOCUMENTATION:

Practices to control contamination and *cross-contamination* at *recovery must* be utilized as described and *recovery agencies must* document these significant steps. *Recovery records* (forms) *must* reflect the sequential *recovery* of all *tissues* and there *should* be a written statement to acknowledge “*zone recovery techniques* were utilized.” The individual zones for each *donor must* be identified on the paperwork so all processors can utilize this information along with the results of the *pre-sterilization/pre-disinfection cultures*. The order of *recovery* of each zone cannot be prescribed but the sequence of zones *must* be recorded in the *recovery records*. It is recommended that order of *recovery* within a zone be recorded. Any *deviation* from established protocols for *isolation draping*, *zone recovery*, or *sequencing*, *must* be approved by a *responsible person* and details documented.

*Records must be maintained and shared demonstrating that pre-established suitability parameters for the recovery site were determined to be acceptable prior to tissue recovery. See “Sample Tissue Donor Recovery Site Assessment Form” in this appendix.*

## **Pre-sterilization/pre-disinfection Cultures Results**

### **RESULTS REPORTING AND SHARING:**

To facilitate *tissue* suitability determinations, *pre-sterilization/pre-disinfection cultures* results *must* be provided to recovery agencies by testing laboratories or *tissue* processors within a reasonable amount of time after *recovery*.

Knowledge of a *donor’s pre-sterilization/pre-disinfection cultures* results could affect the eligibility determination made by different processors. Therefore, recovery agencies *must* share relevant *tissue recovery* culture information (*pre-sterilization/pre-disinfection cultures*) with all tissue establishments who are known to have also *recovered tissues*, or to have received *recovered tissues*, from the same *donor* (see D4.300). Procedures *must* be used that describe how this information is received and disseminated in a timely fashion so that proper *tissue* disposition decisions can be made. The “Current Good Tissue Practices for Human Cells, Tissues, and Cellular and Tissue-Based Product Establishments, Final Rule<sup>1</sup>” (CGTPs) describes the need for *procedures* for sharing of results from the same *donor* that relate to the possible contamination of the product or potential transmission of disease [at §1271.160 Quality Program, (b) Functions (2)]. For details regarding expectations for sharing of *records*, refer to B1.500, D4.300, F3.100, J1.200, and K1.100.

### **PATHOGENIC, HIGHLY VIRULENT MICROORGANISMS:**

Two *microorganisms* (and others that have been identified for specific *tissue* types, see E2.800), are considered pathogenic, highly virulent organisms. Individual *tissues* with culture results yielding *Clostridium* or *Streptococcus pyogenes* (group. A strep.) *should* be discarded (see K2.310). Other individual *tissues* from the same *donor* that were *recovered* under conditions that could result in *cross-contamination* *should* also be discarded unless they can be treated with a *validated sterilization* process (see K2.320). Tissue establishments (i.e., processors) that determine final *donor* eligibility *may* consider that more *microorganisms* fit this classification.

## **Considerations**

### **CULTURING METHODS:**

There are different *pre-sterilization/pre-disinfection culturing* methodologies in use. The filter-culturing technique that is used for *tissue* types such as *cardiac tissue* (C) and *vascular tissue* (V) has a sensitivity that is likely higher than that experienced by the swabbing techniques that are most popular for use with *musculoskeletal tissue* (MS) types. Establishing quantifiable bioburden, actual colony forming units per mL (CFU/mL), can be accomplished via filter-culturing and fluid-extraction techniques<sup>2</sup> but not by limitations of swabbing techniques and protocols used. The low accuracy, sensitivity, and reliability of swab culturing<sup>3-11</sup> plays heavily upon the decision to discard *tissues* with positive cultures of pathogenic, highly virulent *microorganisms*, since the level of bioburden cannot be established. Also, a negative swab culture may be a false negative result and any result can under-represent all organisms present<sup>3-11</sup>. This is especially suspect if one *tissue* grows *Clostridium* or *Streptococcus pyogenes* yet another *tissue* sequentially *recovered* in the same *recovery* zone does not. *Validated sterilization* processes *must* be in place to allow *processing tissues* meeting this scenario.

## PROCESSING METHODS:

Generally, there are two *processing* methods: *disinfection* and *sterilization*. If a *tissue* type is *processed* in a fashion where it is not *sterilized*, only *disinfected* [e.g., *cryopreserved* (MS) like tendons, (OA), (C) and (V)], then considerations *must* be made if there is an associated culture result from that *donor* that is considered pathogenic, highly virulent. If *tissue recovery* controls are in place and documented that offer assurance that *cross-contamination* did not occur, then that *tissue may* be suitable if its own culture result is acceptable. If such controls are not in use and documented (i.e., *sequencing*, *zone recovery*, trauma recovery protocols such as *isolation draping*), the intent of this appendix is to discard all *tissues* that were only *disinfected* (not *sterilized*).

## References

1. 21 CFR Part 1271 Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule, Department of Health and Human Services, FDA, November 24, 2004.
2. Ronholdt CJ, Bogdanský S: "A Fluid Extraction Technique for Detection of Microbial Contamination on Human Allografts"; AATB Posters and Abstracts, 28<sup>th</sup> Annual Meeting (2004).
3. von Garrel T, Knaepler H, Mutters B: "Quality of Microbiological Testing Methods for Evaluation of Bacterial Contamination of Allogeneic Cancellous Bone Grafts"; AATB Abstracts, 16<sup>th</sup> Annual Meeting (1993), and, in *Transfusion*, Vol. 33, No. 7, 1993.
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6. Veen MR, Bloem RM, Petit PL: "Sensitivity and Negative Predictive Value of Swab Cultures in Musculoskeletal Allograft Procurement"; *Clinical Orthop*, 259-63, 1994.
7. Perry JL: "Assessment of Swab Transport Systems for Aerobic and Anaerobic Organism Recovery"; *Journal of Clinical Microbiology*, May 1997, p. 1269-1271.
8. Perry JL: "Inhibitory Properties of a Swab Transport Device"; *Journal of Clinical Microbiology*. Vol. 35, p. 3367-3368, 1997.
9. Wilson DA, Tuohy MS, Procop GW, Hall GS: "Effects of Storage Temperature on the Recovery of Bacteria from Three Swab Transport Systems..."; Abstracts, American Society for Microbiology, 101<sup>st</sup> General Meeting, May 2001.
10. Mills AR, Roberts MR: "Evaluation of Culturing Methods at Predicting Allograft Sterility for Aseptically Processed Tissue"; AATB Posters and Abstracts, 25<sup>th</sup> Annual Meeting (2001).
11. Ronholdt CJ, Bogdanský S: "Quantitative Microbial Comparison of Swab Culturing Systems on Human Allografts"; AATB Posters and Abstracts, 28<sup>th</sup> Annual Meeting (2004).

## Sample Tissue Donor Recovery Site Assessment Form

**Tissue Donor ID #:** \_\_\_\_\_ **Recovery Site Name:** \_\_\_\_\_

**Recovery Site Location** (circle one):

Dedicated Tissue Recovery Site

Healthcare Facility Operating Room

Autopsy Suite

Other Area (describe): \_\_\_\_\_

Check the appropriate box. Any "No" answer *must* be described in detail, rectified if possible, and requires review by a *responsible person*.

<b>Pre-Recovery Evaluation:</b>		Yes	No
1.	Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.		
2.	Adequate lighting to perform physical assessment and tissue recovery is present.		
3.	Adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash is present.		
4.	The recovery area has a controlled, closed airflow system. This means there is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (i.e., doors, windows that can open, fans, air conditioners, etc.); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields.		
5.	The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.		
6.	Signs of insects, rodents, or other pests are not visible.		
7.	Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, are not present.		
8.	The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of tissue.		

<b>Concurrent with Recovery:</b>		Yes	No
1.	Human traffic is restricted and all personnel entering the recovery area are properly outfitted and their movement controlled.		
2.	Other activities (e.g., embalming, autopsy, another tissue donor recovery) did not occur simultaneously in the same room as this tissue recovery.		
<b>Post-Recovery Activities:</b>		Yes	No
1.	All contaminated/biohazardous re-usable supplies were decontaminated, and adequately contained for transport, and that contaminated/biohazardous waste was properly disposed, or contained and transported to a disposal site.		
2.	All working surfaces and the floor were cleaned using approved solutions and equipment.		

Comments: \_\_\_\_\_

**The above parameters have been met and the *recovery site* has been determined to be suitable (check one):**    Yes \_\_\_\_\_ No \_\_\_\_\_

Completed By: \_\_\_\_\_ Date/Time: \_\_\_\_\_

Document Control No./Date



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