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2 *Guidance Document*

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4 *Creation, Retention, and*

5 *Security of Images Used in*

6 *Tissue Banking*

7 *[No. 11, xxx]*

8 *Certain American Association of Tissue Banks (AATB) guidance documents describe mandatory requirements with*
9 *which accredited tissue banks must comply fully, whereas other AATB guidance documents present only*
10 *recommendations regarding possible approaches, but not necessarily the only approach, for compliance by*
11 *accredited tissue banks with AATB Standards. **This guidance document is advisory in nature only, and does not***
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17 *recommendations do not represent the sole approach, and alternative approaches may be satisfactory to establish*
18 *compliance with Standards. This guidance document is intended solely for the use of AATB accredited tissue banks*
19 *in conjunction with the AATB's Standards for Tissue Banking.*

20 *American Association of Tissue Banks*
21 *8200 Greensboro Drive*
22 *Suite 320*
23 *McLean, Virginia 22102*
24 *(703) 827-9582*

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

5 American Association of Tissue Banks
6 8200 Greensboro Drive
7 Suite 320
8 McLean, Virginia 22102
9 www.aatb.org

10
11 For questions on the content of the document, please contact the AATB at:

12 (703) 827-9582

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29 practices. However, for several reasons, they may not be. As new developments in the practice
30 of tissue banking occur, changes may be recommended to the *Standards*. It is not possible,
31 however, to revise each publication at the time such a change is adopted. Thus, it is essential
32 that the most recent edition of the *Standards* be consulted as a reference in regard to current
33 acceptable practices. The AATB expressly disclaims any liability arising from any inaccuracy or
34 misstatement herein.

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

Justin Bezner (Lead)

Patrick AbdelMessih

Beverly Bliss

Jeff Cox

Ed Ferreol

Glenn Greenleaf

Ronda Horstman

Louis Jares

Korinna Kellerstrass

Rhiannon Knueven

Curtis Lee

Joel Osborne

Lisa Paolillo

Sam Ramos

Gregory Ray, MD

Mike Real

Walter Recker

Brian Roe

Jon Boyd (AATB liaison)

Jason LoVerdi (AATB liaison)

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1 **AATB GUIDANCE DOCUMENT**
2 **Creation, Retention, and Security of Images Used in Tissue Banking**
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5 **I. INTRODUCTION**
6

7 **A. History and Purpose**
8

9 *Images* are commonly collected by AATB members in connection with the coordination,
10 recovery and distribution of tissue for transplant. *Images* are used to meet regulatory
11 requirements and ensure the quality and safety of tissue and training. Some examples of how
12 *images* are used include documentation of donor identification, to determine donor eligibility,
13 provide documentation for use by a coroner or medical examiner in a medical-legal case,
14 documentation of a thorough and proper donor reconstruction, documentation of the donation
15 process for use in training, education, and research, and documentation of the evaluation and
16 outcome of tissue processing and final packaging.
17

18 AATB *Standards for Tissue Banking* require that the document of authorization include
19 authorization for the capture of “photographic or other imaging” if it is the practice of the tissue
20 establishment to capture these *images*. Additionally, while not specifically referencing *images*,
21 *Standards* address the requirements for maintaining electronic records including the ability to
22 ensure data integrity, retrieval of electronic data, and retention of the data.
23

24 The creation, retention and security of *images* present challenges that all organizations should
25 consider. These considerations include thoughtful evaluation of the type of device used to create
26 the *image*, how these *images* will be used and evaluated, methods for securely transferring
27 *images* from the initial device to subsequent devices, short and long-term storage methods, and
28 the security and reliability of the entire process. Every tissue bank should have employee
29 confidentiality policies that ensure records are handled appropriately by staff. Establishing
30 written policies and procedures with medical examiners/coroners regarding obtaining and
31 handling *images* should be considered a best practice. *Images* used for donor eligibility
32 evaluation must be retained as part of the permanent donor record in accordance with required
33 record retention policies and procedures.
34

35 The following Guidance Document is provided to assist AATB accredited organizations when
36 establishing policies and procedures related to the capture and control of *images*. Due to rapidly
37 evolving technology, organizations should periodically evaluate their policies and procedures.
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1 **B. Definitions:**

2 As used in this Guidance Document and, where relevant in *AATB Standards*, the following
3 definitions apply:

4 **Chain of Custody** – The chronological documentation or paper trail showing the full process of
5 acquisition, control, transfer, handling and disposition of physical or electronic materials.

6 **E2EE** – End to End Encryption is a process that encrypts data at the beginning of the
7 information broadcast and has a 2nd un-encryption step on the receiver's end.

8 **FTP** – File Transfer Protocol is a standard network protocol used for the transfer of computer
9 files between a client and server on a computer network.

10 **FXP** – File Exchange Protocol allows the transfer of files from one FTP server to another FTP
11 server using an FXP client. The data is transferred from one remote FTP server to another inter-
12 server without routing the data through the client's connection.

13 **Image(s)** – A representation of the external form of an object, place or person in a photographic,
14 digital or videographic format.

15
16 **Metadata** – A set of data that describes and gives information about other data. With digital
17 *images*, this would be additional data inserted into an *image file* that captures information about
18 the *image* at the time it was captured. This can include geotagging (the location of the camera at
19 the time of photography), date and time, and the device the *image* was captured on.

20 **Third Party** – A previously established stakeholder organization that has an interest in accessing
21 and/or viewing donor *images*. These can include a coroner / medical examiner office, another
22 donation organization, and/or a funeral home.

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II. Authorization

The AATB *Standards* related to authorization, specifically, D2.400 Core Elements for Authorization, require that when photographs or other *imaging* are obtained, the document of authorization include adequate information explaining that the recovery of tissue requires photographic or other *imaging*. See D2.400.6) e). Language authorizing the capture of *images* should be included in all authorization forms as the need to obtain *images* may not be known at the time of authorization. The following is sample language that may be included in the authorization template:

I authorize all necessary imaging, which may include photographs, digital images and other media (collectively “images”) and the use of images in accordance with [insert recovery agency’s name] policies, including for the determination of medical eligibility, quality assurance activities, research, training and education. I understand that images may be disclosed to qualified third parties.

Staff responsible for obtaining authorization or disclosing authorization should be trained to respond to questions regarding the (i) types of entities and individuals that may be provided access to the *images*; and (ii) purposes for which *images* may be used. Examples of entities or individuals that may be provided access to *images* include:

- Organizations that convert the donated tissue into grafts that will be transplanted into recipients (tissue processors);
- Researchers utilizing tissue donated for research purposes to advance transplantation and medical treatment and therapy; and
- Medical examiners or coroners if the death is under their jurisdiction.

Examples of purposes for which *images* may be accessed by *third parties* may include:

- To review the quality of work either at [insert recovery agency name] or the organizations working to convert the tissue into grafts for transplantation;
- Education for staff at [insert recovery agency name] or the organizations working to convert the tissue into grafts for transplantation, to ensure the gift and future gifts are maximized;
- To assess the medical eligibility of the tissue for transplantation; and
- In medicolegal cases as evidence.

1 III. Image Confidentiality, Security and Storage

2 A. Overview and Device Selection

3 Based on the sensitive nature of *images* used in the coordination, recovery and distribution of
4 tissue for transplantation, confidentiality and security of *images* should be a priority for any
5 organization capturing and storing *images*. Consistent with general confidentiality obligations,
6 confidentiality policies addressing the types of permissible devices, security measures and
7 disclosure to *third parties* can be developed to provide guidance for employees responsible for
8 capturing and working with *images*. Safety measures for each individual establishment should be
9 referenced when taking *images*.

10 Tissue banks should implement procedures for the release of *images* to *third parties*, which may
11 be the same as procedures for the release of any information from a donor record. Some tissue
12 banks may even choose to consult with their general counsel before agreeing to share *images*
13 with a *third party*.

14 There are several devices available for capturing *images*. Only secure devices should be
15 considered for use. Organizations that capture *images* may consider the following when selecting
16 a device: 1) Should the device include broadcasting capability (e.g., Wi-Fi, cell network,
17 Bluetooth)? Many devices on the market today, including cameras, cell phones, tablet devices,
18 and computers may all have the option to broadcast data between devices, computers, and
19 storage servers. A tissue bank may choose to also utilize equipment that does not have broadcast
20 capability, but instead, records *images* to solid media such as a memory card or memory stick. 2)
21 Should the device include active security and encryption capability? State and local laws may
22 address requirements for encryption of identifiable *images* (*images* including identifying features
23 of the donor).

24 The following are examples of devices currently used for *images*: A dedicated camera (can vary
25 from basic point-and-shoot camera to a more complicated Single Lens Reflex device), cell
26 phones by various manufacturers (may or may not communicate with cell network or Wi-Fi),
27 tablet PCs such as iPad® (FaceTime and camera), GoPro®, a dedicated video camera designed
28 for capturing and saving video files (e.g., Flip Video®, and iPod) with or without broadcasting
29 capability.

30 B. Capturing *Images* and Transmission to Storage Media

31 There are many technical considerations when selecting a device to capture *images*, and by
32 association, there are several options regarding how those *images* are stored (on the device or
33 ancillary equipment) and transmitted internally and to *third party* organizations. While AATB
34 does not recommend any particular method for selection of storage media, the following tables
35 outline the advantages and disadvantages of various types of media that tissue banks have used
36 to transmit or share *images* between devices and organizations. Most of these media options fall

1 into two categories: 1) Physical media such as memory cards, USB drives, CDs, and computer
 2 drives; and 2) Internet, or cloud, based media which for the purposes of this Guidance Document
 3 can include file sharing software, e-mail, and any wireless method for sharing *images*.

4 **Table 1: Transmission of *Images* to Physical Media**
 5

	Advantages	Disadvantages
<p>Physical Media (Overview)</p> <p><i>Examples of media types are listed below</i></p>	<ul style="list-style-type: none"> • Low risk of broadcasting data to a <i>third party</i> unintentionally • Cost effective and readily available • Avoids e-mail or other file transfer methods that use the internet 	<ul style="list-style-type: none"> • Can be lost or stolen during shipping or transfer, even when <i>chain of custody</i> is followed • Files can be lost if terminal or disc corrupted due to water damage, heat, or other environmental risks • Not effective for “real time” collaboration if files cannot be broadcasted or shared wirelessly • There is risk that media can be copied without authorization • Encryption on some physical media is limited • Portable memory devices such as USB drives, SD cards, or CDs must be purchased, be available, and remain accounted for
<p>Portable Memory Devices</p> <p><i>(e.g., SD card, micro SD card, USB “thumb” drive)</i></p>	<ul style="list-style-type: none"> • Cost is minimal • Easy to use on portable devices and computer terminals; can often be encrypted using software that is readily available (e.g., BitLocker®) • Controlled password to un-encrypt files for use by authorized individuals only 	<ul style="list-style-type: none"> • May be easy to misplace or lose • End users may not have the proper hardware or software to read the [encrypted] media. • After deleting <i>images</i>, past files may still be readable using file-restoration software

<p>Computer Hard Drive</p>	<ul style="list-style-type: none"> • Readily available due to ubiquity of laptops, computer terminals, and electronic donor documentation • Easy to use; computers are typically maintained and secured by Information Technology (IT) departments • Can be protected with security and encryption software • <i>Images</i> can be transmitted to and from a computer hard drive using secure hardware or wireless means 	<ul style="list-style-type: none"> • A computer must be available to store and share <i>images</i> • Not as convenient as lighter, portable devices • <i>Images</i> can be lost if hard drive fails and no back-up is available • After deleting <i>images</i>, past files may still be readable using file-restoration software
<p>Cloud Storage</p>	<ul style="list-style-type: none"> • Easy transmission and storage of data • Large potential storage capacity • Multiple, convenient interfaces to access files 	<ul style="list-style-type: none"> • It is incumbent on the tissue bank to confirm that files are kept confidential and that the provider employs adequate, effective security measures • Effective control of which personnel have access to file interfaces
<p>Burning <i>Images</i> to CD</p>	<ul style="list-style-type: none"> • Cost is minimal • Not complicated to use • Can potentially be encrypted 	<ul style="list-style-type: none"> • Some computers may not have CD ROM capabilities • CD can be damaged/scratched and rendered unreadable if not protected by a case • Can be lost in transit or during shipping
<p>Printing <i>Images</i> on Paper Documents</p>	<ul style="list-style-type: none"> • Cost is minimal • Not complicated to use • Requires very little training 	<ul style="list-style-type: none"> • Storage requires large amounts of space • Can be costly; quality of ink and paper • <i>Images</i> cannot be encrypted and if lost can easily be viewed by an unintended <i>third party</i> • <i>Image</i> quality could be an issue over time

Shipping Physical Material Using Traceable Method (e.g., FedEx)	<ul style="list-style-type: none"> • Shipment confirmation with availability of notification; shipment, delivery/receipt, signature required upon delivery, etc. 	<ul style="list-style-type: none"> • If lost can easily be viewed by an unintended <i>third party</i> • Time-consuming for shipment and delivery • Can be costly
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Table 2: Transmission of *Images* Using Wireless/*Non-Physical Media*

	Advantages	Disadvantages
Wireless & Internet Based Transfers of <i>Images</i> (Overview) <i>Examples of transfer types are listed below</i>	<ul style="list-style-type: none"> • Common • Relatively easy to perform • Can be performed quickly • Familiar process to the majority of people and organizations 	<ul style="list-style-type: none"> • Security is the greatest risk factor • Secure method of file transmission is a necessity
Texting or Messaging Applications (“Apps”)	<ul style="list-style-type: none"> • Built in security features on select mobile phone OS • Mobile Device Management (MDM) software installation option • Apps available for <i>end-to-end encryption (E2EE)</i> • Convenient for onsite consultations 	<ul style="list-style-type: none"> • <i>Images</i> can be inadvertently sent to an unintended <i>third party</i> • Various levels of built-in mobile phone OS security dependent on device manufacturer • Costs associated with <i>E2EE</i> apps and MDM software
Live Video Streaming	<ul style="list-style-type: none"> • Built-in <i>E2EE</i> between iOS users • Video is not saved on iOS device using FaceTime® • Confirmation of intended recipient through live video feed • Convenient for onsite consultations 	<ul style="list-style-type: none"> • Ability to screen-capture unauthorized video still <i>images</i> • Video can be recorded using a <i>third party</i> video capture app

Wi-Fi	<ul style="list-style-type: none"> • Secure network allows immediate upload of <i>images</i> to cloud storage • Secure Virtual Private Network (VPN) option • MiFi cell based networks with VPN connection can be secure and convenient for consultations • Inexpensive 	<ul style="list-style-type: none"> • It is incumbent on the tissue bank to confirm that files are kept confidential and that the provider employs adequate, effective security measures • Effective control of which personnel have access to file interfaces
E-mail <i>(Private company and/or secure server)</i>	<ul style="list-style-type: none"> • Secure • E-mails are saved on server 	<ul style="list-style-type: none"> • Degree of security is dependent on organization's security level • Potential human error to send e-mails to unintended recipients. • E-mail has potential to be hacked
Secure File Transfer Software <i>(e.g. ShareFile or DropBox)</i>	<ul style="list-style-type: none"> • Encrypted and/or HIPAA compliant software available • Easy and quick sharing 	<ul style="list-style-type: none"> • Less expensive software or cloud based system pose a higher security risk • Secure software can be cost prohibitive
FTP (client/server), FXP (server/server)	<ul style="list-style-type: none"> • Transfers avoid <i>third party</i> software • Transfer process is quick with proper equipment and setup 	<ul style="list-style-type: none"> • Time consuming • IT assistance and IT commitment may be required • Open <i>FTP</i> addresses pose a high risk for viruses and malware • Equipment may be costly

1
2 *Metadata* is the background data inserted into an *image* file at the time it was captured. It is
3 recommended that each tissue bank consult with its IT department to determine which types of
4 *metadata* should be captured. Determination of how to handle *metadata* during file transmission
5 and storage should be made with attention to the impact on confidentiality and evidentiary value.

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1 **C. Long-Term Storage of Images**

2 The short and long term storage of *images* should be done according to accepted standards of
3 donor record retention when *images* are used for purposes of donor eligibility. *Images* captured
4 for any other reason (e.g., following donor reconstruction) can be determined at the discretion of
5 the tissue bank.

6 **D. Destruction of Images**

7 A tissue bank may determine that it does not want to keep *images* in perpetuity. A procedure
8 governing the storage and potential destruction of *images* according to a schedule should be
9 determined by the tissue bank. It should be noted that files that are digitally deleted can often be
10 re-captured using file restoration software. Therefore, it is in the best interest of the tissue bank
11 to consult with its IT department and/or utilize software or utilities designed to permanently
12 delete and overwrite files after deletion. In cases where *images* are captured on physical media,
13 such as CD or paper, the tissue bank should continue to utilize processes already in place to
14 destroy confidential records.

15

16 **IV. Best Practices: Photography Methodologies**

17 **A. General**

18 *Images* should be captured in a manner that enables the viewing party to clearly identify the
19 anatomic or physical location of the captured item. The capture of *images* should follow protocol
20 established within the individual agency/organization in accordance with internal policies,
21 procedures and practices, including policies related to staff safety, and subject to conditions
22 existing in the environment at the recovery site.

23 **1. Lighting:** *Images* should be taken in areas with sufficient indirect lighting to permit clear
24 visualization without overexposure, which would wash out the area(s) being captured.

25 The correct white balance setting should be selected on the camera to compensate for
26 fluorescent or incandescent lighting. Verifying that a known white object in the *image*,
27 e.g. a piece of paper, looks white in the final *image* is an effective way to check the color
28 balance.

29

30 **2. Anonymity:** *Images* of the face or areas containing means of identification should be
31 avoided if not essential to the purpose of the *image*.

32

33 **3. Photo Scale/Identifier:** A measuring tool, such as a ruler or placard, and a donor
34 identifier, such as the donor number, should be used when *images* are captured for
35 screening/eligibility, forensic or investigative purposes to assure the preservation of

1 evidence. This scale provides an accurate source of reference for visualization and the
2 ability to scale measure the size of elements in the *image* in a scientific manner. The
3 photo scale should be placed near the area being captured to provide an accurate point of
4 reference.

5
6 **4. Equipment:** Appropriate equipment for capturing *images* should be defined by the
7 individual agency/organization. Considerations related to selection of equipment are
8 outlined above in Section III. Image Confidentiality, Security and Storage. Personal
9 devices used for *images* may be accessed and used by *third parties* when used for *images*
10 that may be relevant to legal proceedings.

11
12 **5. Editing:** *Images* taken for the purpose of evaluation by a medical examiner, coroner or
13 pathologist may be edited if permitted by policies and procedures or at the request of the
14 medical examiner/coroner.

15
16 **B. Identification**

17 In accordance with policies and procedures, the means of identification should be captured with
18 minimal inclusion of outside, unnecessary *images/items*.

19 **C. Belongings & Chain of Custody**

20 *Images* may be used to document the *chain of custody* of donor personal belongings, and the
21 condition of belongings and samples/specimens being moved or transported with the body.
22 *Images* of belongings or samples received with the body should be captured prior to the
23 alteration or removal of any items from the initial state of the body or its surroundings at receipt.
24 *Images* of belongings or samples to be transported or moved with the body following tissue
25 recovery should be captured in the manner in which they are left by the tissue recovery staff.
26 These *images* may be used as verification of the organization's appropriate handling and transfer
27 of the belongings and specimens.

28 *Images* should include items in their original, unaltered state and should not include identifying
29 characteristics unless required to assure all items are documented.

30 **D. Reconstruction**

31 Organizational practices may require the capture of *images* for documentation of the donor prior
32 to and/or following recovery. This may be done to provide documentation of the donation or
33 reconstruction process.

34 *Images* should include the entire surgical site prior to and following recovery.

35

1 **E. Family Requests**

2 In rare circumstances the legal next-of-kin may request specific *images* of the donor, such as
3 photographs of tattoos. Such requests should be handled on a case-by-case basis in accordance
4 with established organizational policy.

5 **F. Screening & Eligibility**

6
7 **1. External Findings:** Physical findings during donor eligibility evaluation and/or recovery
8 may require further evaluation by the Medical Director to determine donor eligibility.
9 *Images* should be captured in a manner which provides a frame of reference as to location
10 on the body and another close-up *image* with detail to enable a more concise evaluation.
11 For example, if there is a concerning skin lesion discovered on a donor’s back during the
12 physical assessment, the *image* should encompass the entire back and another within
13 close range to further illustrate the detail of the area of concern.

14
15 **2. Internal/Intra-Operative Findings:** Findings may be discovered during tissue recovery
16 requiring *images* of an area within a sterile field. Care must be taken to avoid
17 contamination of the surgical field. If a close range *image* is essential, photography
18 equipment should be utilized in a manner which maintains the integrity of the sterile field
19 and sterile team members. If available, a sterile ruler or scalpel handle with a ruler may
20 be included in the field to provide scale. Actions and movements should be in accordance
21 with AORN standards and guidelines and follow the guidelines set forth in the AATB
22 Aseptic Technique Guide.

23
24 **G. Medical Examiner/ Coroner/ Pathologist**

25 **1. Background:** Donors may fall under the jurisdiction of a medical examiner, coroner or
26 forensic pathologist. Tissue recovery may cause alteration to belongings or the donor’s
27 physical appearance. The medical examiner, coroner or forensic pathologist may request
28 *images* to preserve evidence or the *chain of custody*.

29 In these cases, *images* should be taken upon obtaining possession of the body, prior to the
30 removal of any medical/therapeutic artifacts, clothing or belongings, and after the
31 removal of items within the recovery field but before sterile preparation for surgery.
32 Items not interfering with the surgical recovery sites or in areas of injury related to the
33 cause of death should be left in place for further evaluation by the party holding
34 jurisdiction and following surgical preparation/shaving.

35 **2. Full Body Images:** *Images* should be scaled and include each surface of the body. While
36 the anonymity of the donor should always be respected, *images* for investigative purposes
37 should not exclude any detail including identifying traits or characteristics. Full body or

1 overall *images* should include all aspects of the body utilizing a technique which provides
2 an accurate perspective and a range which provides sufficient detail for review and
3 identification of all findings for investigative purposes. For example, capturing *images* of
4 each plane of the body (anterior, posterior, left and right) and in thirds (head to mid-torso,
5 mid-torso to mid-thigh, and mid-thigh to foot.)
6

7 **3. Injuries:** *Images* should be captured at close range and scaled to provide a more detailed
8 *image*.

9
10 **4. Identification:** *Images* should include a means of reference for identification or the
11 decedent's name. This could be a UNOS number or tissue identification number with
12 corresponding documentation connecting the ID number with the donor name.
13

14
15 **5. Organ and Tissue Cases:** In some circumstances *images* may be required on shared
16 organ and tissue cases which may include the capture of *images* of the donor on a
17 hospital unit prior to organ procurement. In such situations, the donor may be unstable
18 and altering the position of the body may have adverse effects such as shifting medical
19 devices critical to donor stability. Under such circumstances, it may be acceptable to
20 complete partial *image* capture (anterior, left and right) to avoid excessive manipulation.
21 *Images* of the posterior aspect of the donor may then be completed following the organ
22 procurement and prior to surgical preparation for tissue recovery.
23

24 **6. Intraoperative Images:** Injuries or abnormalities may be captured during recovery to
25 document findings that may be relevant to a medico-legal case.
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29