



Guidance Document

Tissue Donor Physical Assessment Form

[No. 1, version 2, June 27, 2005]

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

***American Association of Tissue Banks
Suite 450
1320 Old Chain Bridge Road
McLean, Virginia 22101
(703) 827-9582 (703) 356-2198 Facsimile***

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

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

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

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

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

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

TABLE OF CONTENTS

I.	Introduction	4
II.	Standard Operating Procedure	4
	A. Purpose	4
	B. Definitions	5
	C. Materials	5
	D. Safety	5
	E. Instructions for Completing Page 1	5
	F. Instructions for Completing Page 2	9
	G. Notes	9
	H. References	10
	I. SOP Historical Changes	10
III.	Sample Tissue Donor Physical Assessment Form	13
IV.	Example of Completed Form	15

AATB GUIDANCE DOCUMENT

TISSUE DONOR PHYSICAL ASSESSMENT FORM

I. INTRODUCTION

Within AATB's *Standards for Tissue Banking*, there are specific requirements related to tissue donor identification and physical assessment. For instance, Standard D4.210 requires that, "prior to the retrieval of cells and/or tissue from a potential deceased donor, a physical examination 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 hepatitis; or these observations may alert recovery personnel to signs related to an active infection (communicable disease), all of which can affect donor eligibility. Other standards that are related to the significant steps of this process are found in C1.100, C1.500, D4.220, D4.230, D4.240, D4.310, D4.320, D4.330, D4.400, D5.000, D5.100, D5.110, D5.120, D5.200, D5.300, D5.400, and D5.600.

To assist AATB-accredited tissue banks to completely and properly document the physical assessment, the AATB membership developed the attached "Sample Physical Assessment Form" and the corresponding "Standard Operating Procedure (SOP)" as a useful resource. Tissue banks are not required to use this particular form or SOP but can adapt and personalize them for use. Tissue donor physical assessment is a significant step in the donor eligibility process therefore staff training and evaluation of competency is indicated.

II. STANDARD OPERATING PROCEDURE

A. Purpose

The purpose of this SOP is to describe how to properly complete the two-page AATB Sample 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 suitability in order to proceed with tissue recovery. (See standards D4.210, D4.220, D4.230, and D4.310)

This form shall be completed in its entirety, prior to retrieval of tissues. This record identifies the staff involved in each significant step of the physical assessment procedure and documents donor identification and consent (authorization) verification procedures. (See standards D5.110, D5.120, D5.200).

B. Definitions

The following abbreviations are used in this Guidance Document:

- lbs = pounds
- kgs = kilograms
- ft. = feet
- in. = inches
- cm. = centimeters
- ID = identification
- UNOS = United Network for Organ Sharing
- N/A = not applicable
- ET = endotracheal
- NG = nasogastric
- IV = intravenous
- Ortho = orthopedic

C. Materials

The following items and materials will be used:

- Indelible ink pen (black preferred);
- AATB Sample Tissue Donor Physical Assessment Form; and
- Relevant donor medical records, including but not limited to: the consent (authorization) form, the medical history and behavioral risk assessment questionnaire form, and available, relevant records.

D. Safety

Follow established blood borne pathogen precautions.

E. Instructions for Completing Page 1

This page: describes how the donor is identified; provides documentation if there was evidence of previous donation of ocular tissues and/or organs; lists the autopsy plan (if known); documents the recovery team's physical assessment findings using an established list of potential risk factors; offers a general description of the donor's appearance; and, identifies the personnel who verify the donor identification and perform the physical assessment. Information may be derived from available relevant medical records, source documents, and/or personnel involved with the care of the patient/donor.

Step	Action
1	<u>IDENTIFICATION</u> Document the complete name of the donor on the line provided as it is written on the Consent (or Authorization) form.
2	Document the donor's age on the line provided. Circle appropriate selection that follows to designate if this number equals "days," "months," or "years."
3	Document the recovery agency's unique donor ID# on the line provided.
4	If known, document any other agency's unique donor ID# related to this donor on the lines provided. Use appropriate abbreviation to identify the agency on the line before "ID#" then follow this with the actual unique number assigned by that agency.
5	Circle the appropriate selection to designate the sex/gender of the donor, male or female.
6	Document the race of the donor on the line provided (acceptable abbreviations may be used).
7	Enter a number for the weight of the donor followed by circling the appropriate selection designating whether this indicates "lbs." (pounds) or "kgs" (kilograms)
8	Circle the appropriate selection to indicate how this weight was derived: "estimated/team" indicates the donor was not physically weighed, and the team members are visibly estimating the weight; "reported" is circled if the weight is found in relevant medical records and if used, the specific source for this number is documented here; "actual" is selected if the donor was physically weighed. One weight shall be documented and agreed upon. Multiple selections of how the weight was derived can be circled if multiple methods were used, and all agree with the weight recorded here.
9	Enter a number for the height of the donor followed by circling the appropriate selection designating whether this indicates "ft."(feet), "in." (inches), or "cm." (centimeters). Note: Both feet and inches may be used together as long as both words are circled, and there is clear separation (using identifiers) between the two numbers written (i.e., 5' 4").

10	Circle the appropriate selection to indicate how this height was derived: "estimated/team" indicates the donor was not physically measured, and the team members are visibly estimating the height; "reported" is circled if the height used is found in relevant medical records and if used, the specific source for this number is documented here; and, "actual" is selected if the donor was physically measured. One height shall be documented and agreed upon. Multiple selections of how the height was derived can be circled if multiple methods were used, and all agree with the height recorded here.
11	The manner in which the donor was identified is documented by circling the applicable words: "hospital ID band," "toe tag," or "other." "Other" must be described on the line provided. Note: Multiple identifiers may be circled if present. Re-create tag/band containing the most information. All identifying tags/bands should match.
12	The identification band or tag is re-created in the space provided (designated by a generic shape of a tag), or circle the N/A box if no band or tag was present.
13	On the line provided, print the names or initials of the tissue recovery personnel present that confirmed the donor identification. Document the date and time noting when this step was completed.
14	<u>EVIDENCE OF DONATION/AUTOPSY</u> Document evidence of ocular donation by circling the selection that applies: "whole eyes," "corneas only," or "N/A."
15	Document evidence of organ donation by circling "Yes" or "No". If "Yes" is circled, write the UNOS # for the donor on the line provided.
16	Document the plan for an autopsy by circling the selection that applies: recovery is "pre" or "post" autopsy; if an autopsy has been done or is planned, circle the appropriate selection describing it as a "full" or "limited" autopsy; or, circle that "no autopsy planned" or "plan for autopsy unknown," whichever applies.
17	<u>RECOVERY TEAM ASSESSMENT</u> Document by circling the appropriate word, if jaundice is observed ("Yes"), or not observed ("No").
18	Document by circling the appropriate word, if any genital lesions are observed ("Yes"), or not observed ("No").
19	Document by circling the appropriate word, if any enlarged lymph nodes are observed ("Yes"), or not observed ("No").

20	Document by circling the appropriate word, if evidence of any tattoos and/or piercings are observed (“Yes”) or not observed (“No”).
21	Document by circling the appropriate word, if any white spots in the mouth are observed (“Yes”), or not observed (“No”). If unable to visualize the oral cavity, circle ‘unable to visualize’ selection only.
22	Document by circling the appropriate word, if any non-medical injection sites are observed (“Yes”), or not observed (“No”).
23	Document by circling the appropriate word, if evidence of an enlarged liver (hepatomegaly) is observed (“Yes”) or not observed (“No”).
24	Document by circling the appropriate word, if the rectal examination reveals signs of insertion trauma or if perianal lesions are observed, circle “Yes”, or if not found during rectal examination, circle “No.” Circle the word to identify which finding is seen, or both, if applicable.
25	Document by circling the appropriate word, if there are signs of a rash, scab, or skin lesion (non-genital). Circle “Yes” if evidence is found, or if not found, circle “No.” Circle the word to identify which finding is seen, if applicable.
26	Document by circling the appropriate word, if any blue/purple (gray/black) spots/lesions are seen. Circle “Yes” if found, or if not found, circle “No.” Circle the applicable words that identify which findings are seen.
27	Document by circling the appropriate word, if there are signs of trauma or infection to potential (tissue) retrieval sites. Circle “Yes” if evidence is found, or if not found, circle “No.” Circle the word to identify which finding is seen, or both, if applicable.
28	Document by circling the appropriate word, if there are signs of any abnormal ocular finding (e.g., icterus, scarring). Circle “Yes” if evidence is found, or if not found, circle “No.” Circle the word to identify which finding is seen, if applicable, or describe on lines provided next. Also, if “Yes” is selected, appropriate contact with the local Eye Bank and/or your Medical Director is warranted for consultation.
29	On the lines provided, completely explain any listing designated as “Yes” in steps #17 through #28, inclusive. If applicable, also document why any visualization was not possible.
30	<u>GENERAL APPEARANCE</u> Upon initial body assessment, describe the cleanliness encountered by circling either “Good” or “Poor.” Use space provided to fully describe if finding is determined to be “Poor.”

31	On the line provided, print the name or initials of each team member who performed the physical assessment procedure. Document the date and time noting when this step was completed.
32	Print name of the person completing the form in the space provided at the bottom of the form. Sign on the appropriate line, initial, and date the document.

F. Instructions for Completing Page 2

Completion of this page documents all of the physical assessment findings by team members by recording them on anterior and posterior body diagrams. This will include those findings documented on page one plus any other observations made. If no findings are seen on either schematic view, documentation such as “unremarkable” must be made. A summary of the review for recovery suitability is also documented to complete the assessment.

1	Document the recovery agency’s unique donor ID# on the line provided.
2	All gross findings are appropriately drawn on the anterior and posterior body schematics using the lettered Key provided. Blank schematic Key spaces are provided to document gross findings not listed and/or to provide areas to further describe any listing {e.g., (P), (T)}.
3	After the preliminary review of all available medical records and the physical assessment findings are completed, a responsible person from the recovery team must circle either “acceptable” or “not acceptable,” then write their name or initials and date of completion of this process in the spaces provided. If there are no medical records available to the tissue recovery team, draw a single-line strikethrough the words ‘available medical records &’ (e.g., available medical records &), and date and initial this correction.
4	After reviewed for completeness and accuracy, the form is appropriately forwarded.

G. Notes

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.

All documentation concerning "time" should be based on a 24-hour clock (military time). The notations "pm" and "am" should NOT be used, and the current and appropriate time zone for the respective region at the time of recovery will be utilized.

Deviations from written procedures should be documented and shared with all entities who determine tissue and donor suitability.

H. References

Current AATB *Standards for Tissue Banking*, applicable federal regulations.

SOP HISTORICAL CHANGES			
AMENDED BY	EFFECTIVE DATE	PG #	SUMMARY OF CHANGE (S)
SAB/AM/AG	2/23/04		NEW
PA Workgroup/SAB	6/27/05	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 physical assessment: "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 which 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.



Sample Tissue Donor Physical Assessment Form

Identification

Name stated on Consent (Authorization) : _____

Age: _____ days months years Recovery Agency ID#: _____

Sex/gender: Male Female Race: _____ ID#: _____

Weight: _____ lbs. kgs Weight is: estimated/team, reported (source: _____), actual

Height: _____ ft. in. cm. Height is: estimated/team, reported (source: _____), actual

Manner identified by: hospital ID band, toe tag, other (describe) _____

Identification Band/Tag

ID re-created as closely as possible,

or circle N/A (if not present).



Personnel confirming donor identification: _____ Date/time: _____

Evidence of Donation/Autopsy

Eye donation: whole eyes, corneas only, N/A ; Organ donation: Yes No UNOS#: _____

Autopsy: tissue recovery is pre, or post autopsy (full, limited); no autopsy planned; or, plan unknown

Recovery Team Assessment:

Is there evidence of:

- Jaundice _____ Yes _____ No _____
- Genital lesions _____ Yes _____ No _____
- Enlarged lymph nodes _____ Yes _____ No _____
- Tattoo/piercing _____ Yes _____ No _____
- White spots in the mouth _____ Yes _____ No _____ Unable to visualize
- Non-medical injection sites _____ Yes _____ No _____
- Enlarged liver (hepatomegaly) _____ Yes _____ No _____
- Insertion trauma/perianal lesions _____ Yes _____ No _____
- Rash/scab/skin lesion (non-genital) _____ Yes _____ No _____
- Blue/purple (gray/black) spots/lesions _____ Yes _____ No _____
- Trauma/infection to potential retrieval sites _____ Yes _____ No _____
- Abnormal ocular finding (e.g., icterus, scarring) _____ Yes _____ No _____ Unable to visualize

Notes/Explain if "unable to visualize", or if any answers are "Yes": _____

General Appearance

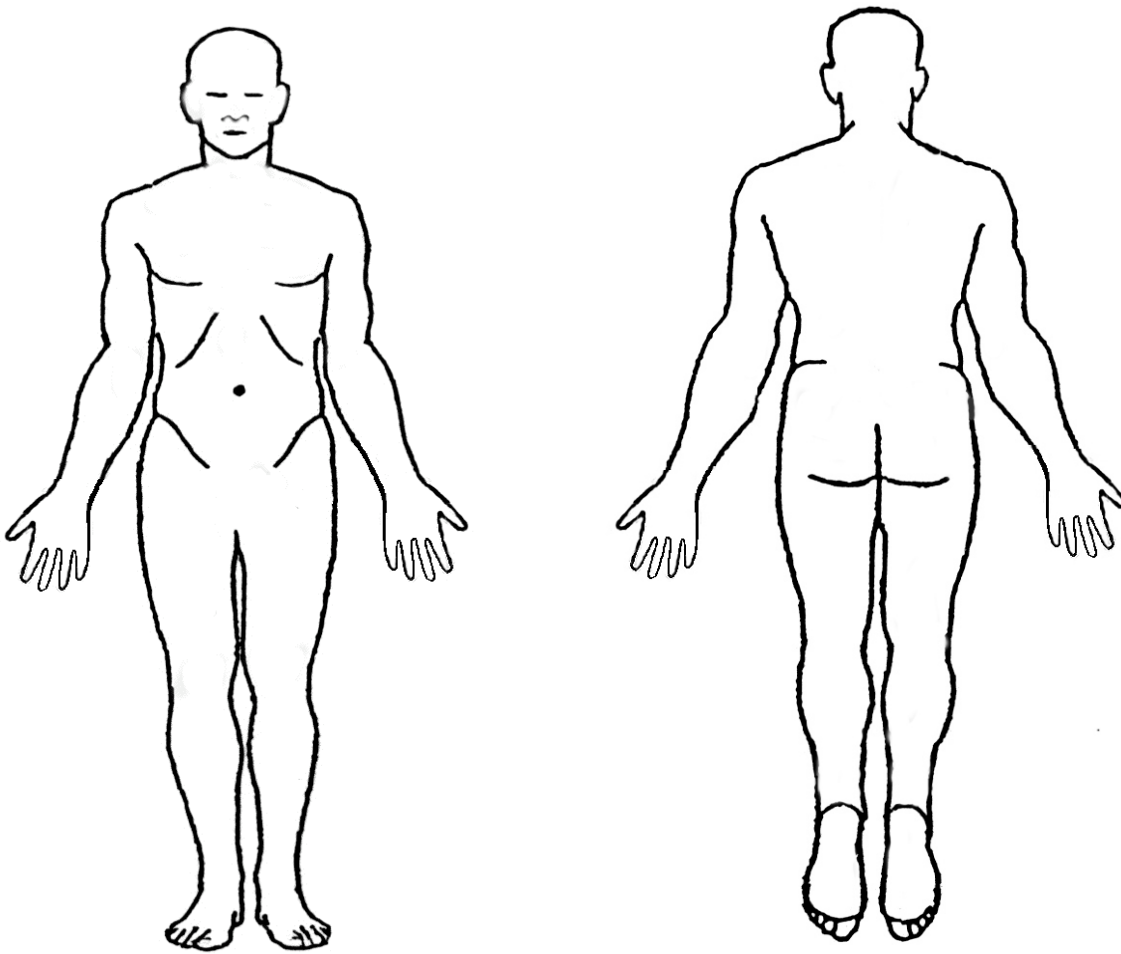
Cleanliness: Good Poor; Describe if "poor" _____

Personnel performing physical assessment: _____ Date/time: _____

Name of Person Completing Form (Print) Signature Initials Date

AATB Sample Tissue Donor Physical Assessment Form
 Recovery Agency ID#: _____

Recovery Team Assessment: (continued)



Key to schematics:

- | | | |
|--------------------------|--|-----------------------------------|
| (A) Abrasion | (J) Team blood draw site | (T) Tattoo – requires description |
| (B) Bruise/Contusion | (L) Laceration/Wound | (U) Urethral catheter |
| (C) Cast/Ortho device | (M) ID band/tag | (V) Skin lesion |
| (D) Dressing/Bandage | (N) Needle entry site | (W) Scab |
| (E) ET tube/NG tube | (O) Organ recovery incision | () _____ |
| (F) Fracture/Dislocation | (P) Body Piercing – requires description | () _____ |
| (H) Hematoma | (R) Rash | () _____ |
| (I) IV/Arterial line | (S) Scar (surgical/trauma) | () _____ |

Summary

A review of available medical records & physical assessment findings were completed & found to be acceptable/not acceptable prior to recovery. _____

(Circle one)

(Responsible person)

(Date/time)



Example - Completed Form

Sample Tissue Donor Physical Assessment Form

Identification

Name stated on Consent (Authorization): John C. Doe

Age: 25 days months (years) Recovery Agency ID#: TB724

Sex/gender: (Male) Female Race: Caucasian LCNW ID#: 60132

Weight: 270 (lbs) kgs Weight is: estimated/team, (reported) (source: LCNW), actual

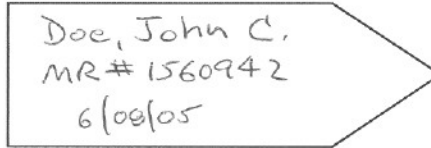
Height: 5'6" (ft) (in) cm. Height is: estimated/team, reported (source: _____), (actual)

Manner identified by: (hospital ID band) toe tag, other (describe) _____

Identification Band/Tag

ID re-created as closely as possible,

or circle N/A (if not present).



Personnel confirming donor identification: Dan May Date/time: 6/9/05 0715 PST

Evidence of Donation/Autopsy

Eye donation: whole eyes, (corneas only), N/A; Organ donation: (Yes) No UNOS#: SJH721

Autopsy: tissue recovery is (pre) or post autopsy (full) limited); no autopsy planned; or, plan unknown

Recovery Team Assessment:

Is there evidence of:

- Jaundice _____ Yes _____ (No)
- Genital lesions _____ Yes _____ (No)
- Enlarged lymph nodes _____ Yes _____ (No)
- (Tattoo)/piercing _____ (Yes) _____ No
- White spots in the mouth _____ Yes _____ No (Unable to visualize)
- Non-medical injection sites _____ Yes _____ (No)
- Enlarged liver (hepatomegaly) _____ Yes _____ (No)
- Insertion trauma/perianal lesions _____ Yes _____ (No)
- Rash/scab/(skin lesion (non-genital)) _____ (Yes) _____ (No) DM 6/9/05
- Blue/purple (gray/black) spots/lesions _____ Yes _____ (No)
- Trauma/infection to potential retrieval sites _____ Yes _____ (No)
- Abnormal ocular finding (e.g., icterus, scarring) _____ Yes _____ (No) _____ Unable to visualize

Notes/Explain if "unable to visualize", or if any answers are "Yes": ET tube in mouth;
tattoo upper right arm; wart back of left hand

General Appearance

Cleanliness: (Good) Poor; Describe if "poor" _____

Personnel performing physical assessment: Fred Ross Date/time: 6/9/05 0735 PST

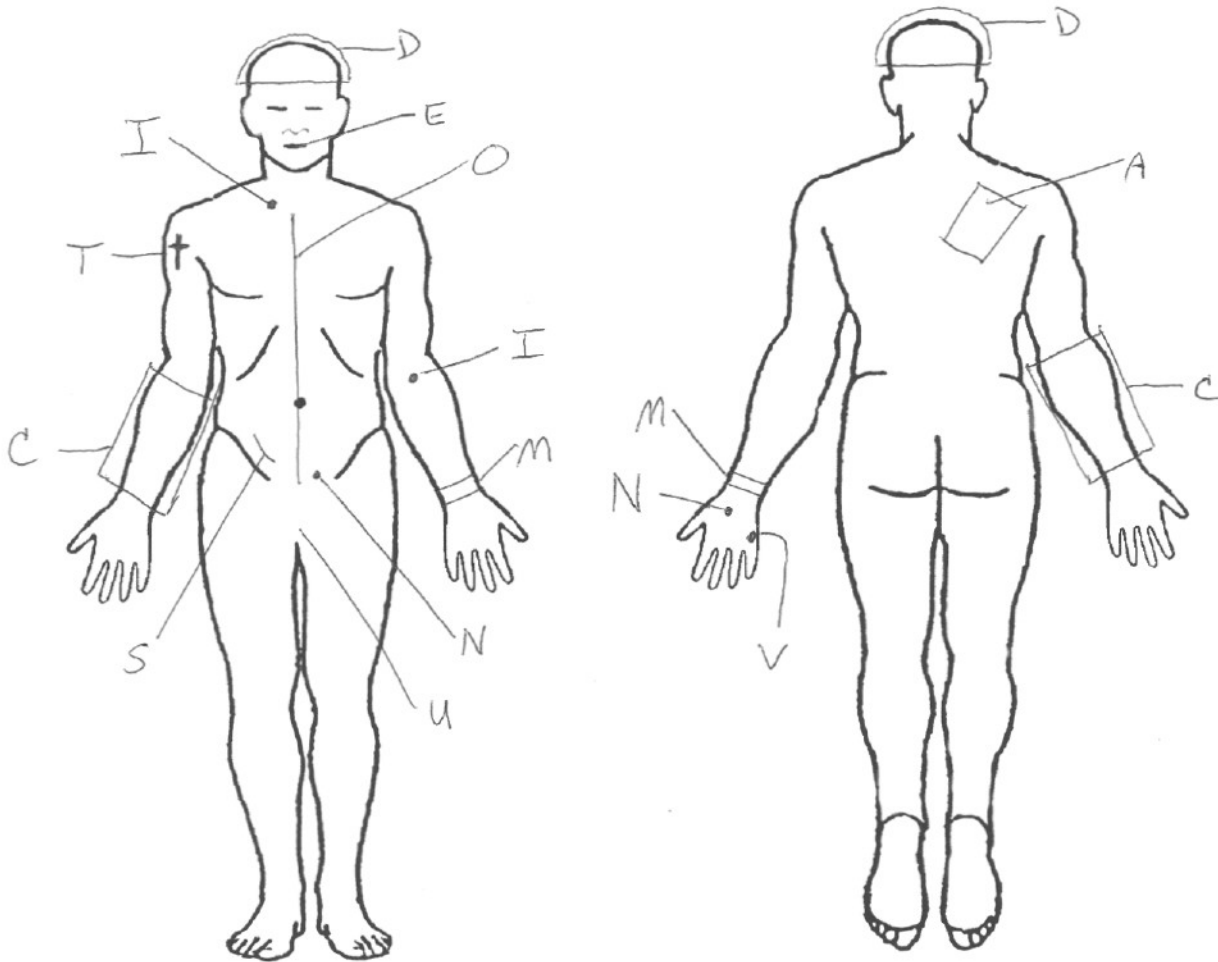
Dan May Dan May DM 6/9/05
Name of Person Completing Form (Print) Signature Initials Date

Example - Completed Form

AATB Sample Tissue Donor Physical Assessment Form

Recovery Agency ID#: TB724

Recovery Team Assessment: (continued)



Key to schematics:

- | | | |
|--------------------------|--|-----------------------------------|
| (A) Abrasion | (J) Team blood draw site | (T) Tattoo – requires description |
| (B) Bruise/Contusion | (L) Laceration/Wound | (U) Urethral catheter |
| (C) Cast/Ortho device | (M) ID band/tag | (V) Skin lesion |
| (D) Dressing/Bandage | (N) Needle entry site | (W) Scab |
| (E) ET tube/NG tube | (O) Organ recovery incision | (T) <u>“cross”- old, homemade</u> |
| (F) Fracture/Dislocation | (P) Body Piercing – requires description | (V) <u>appears to be a wart</u> |
| (H) Hematoma | (R) Rash | () _____ |
| (I) IV/Arterial line | (S) Scar (surgical/trauma) | () _____ |

Summary

A review of available medical records & physical assessment findings were completed & found to be

acceptable / not acceptable prior to recovery. Dan May 6/9/05 0805 PST
 (Circle one) (Responsible person) (Date/time)