



# THE NATIONAL TISSUE RECOVERY THROUGH UTILIZATION SURVEY

## SECTION 5 - Tissue Distribution

The Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), through a contract with the American Association of Tissue Banks, is conducting the 2016 National Tissue Recovery through Utilization Survey (NTRUS).

XXXXXX

Your responses will remain anonymous in the final dataset. While results of this survey will be released in aggregate form and data may be made available in the form of a de-identified dataset, no specific institutional identifiable information will be included.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-xxxx. The time required to complete this information collection is estimated to average 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

## Tissue Distribution

The survey provides definitions for specific tissue types. To facilitate accurate totals, provide counts using the descriptions provided. Use the definitions found at AATB Standard A2.0000 DEFINITIONS OF TERMS. Some terms and/or definitions are new and some have been revised.

To avoid double reporting, please include numbers only for your main facility and your *satellite facilities* (if applicable). The information you are reporting is for the following physical location(s) by name, city and state:

A. name, city, state

B. name, city, state

(need capability for multiple lines/entries)

Which of the following types of tissues did your tissue bank distribute for transplantation:

### TISSUE FROM DECEASED DONORS

HCT/Ps regulated solely under Section 361 of the PHSA

#### musculoskeletal

bone

cartilage (e.g., costal, articular)

meniscus

osteochondral grafts (i.e., an *allograft* consisting of a section, condyle, or plug of bone with an intact articular surface)

osteoarticular grafts (i.e., a large weight bearing *allograft* with intact articular surfaces consisting of a joint with associated soft tissue and bone)

bone + *cellular tissue*

#### soft tissue

fascia lata

ligaments (i.e. patellar)

tendons (e.g., Achilles, gracilis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus)

rotator cuff

pericardium

- nerves
- peritoneal membrane
- dura mater*

cardiac tissue

- valved conduits*
- non-valved conduits*
- patch grafts*
- aortoiliac grafts*

vascular tissue (HCT/Ps regulated solely under Section 361 of the PHSA)

- arteries
- vein grafts*

skin (HCT/Ps regulated solely under Section 361 of the PHSA)

- fresh
- cryopreserved*
- acellular/decellularized
- lyophilized*
- other tissue from deceased donors (specify) \_\_\_\_\_

tissue as a device \_\_\_\_\_

(i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a biological product \_\_\_\_\_

(i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a drug \_\_\_\_\_

(i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

**TISSUE FROM LIVING DONORS**

HCT/Ps regulated solely under Section 361 of the PHSA

- amniotic membrane
- chorionic membrane
- amniotic fluid
- Wharton's jelly
- placental/chorionic disc
- umbilical cord tissue
- umbilical vein
- surgical bone*
- skin for allogeneic use*
- autologous bone*
- autologous parathyroid*
- other *tissue from living donors* (specify) \_\_\_\_\_

tissue as a device \_\_\_\_\_

(i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a biological product \_\_\_\_\_

(i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

tissue as a drug \_\_\_\_\_

(i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

**Indicate how many *finished tissue grafts* were *distributed* to the following:**

hospitals/medical facilities \_\_\_\_\_

*tissue distribution intermediaries* – United States (an intermediary agent in the United States) \_\_\_\_\_

*tissue distribution intermediaries* – International (an intermediary agent outside of the United States) \_\_\_\_\_

physicians/dentists \_\_\_\_\_

another *tissue bank* \_\_\_\_\_

other (specify) \_\_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**

**Did your *tissue bank* provide *tissue* for any of the following:**

medical education/training

Would this *tissue* have been suitable for *transplant*?

always

sometimes

never

research

Would this *tissue* have been suitable for *transplant*?

always

sometimes

never

**MUSCULOSKELETAL DISTRIBUTION**

How many of the following musculoskeletal grafts were *distributed* by your *tissue bank*?  
(Enter 0 if applicable)

**TISSUE FROM DECEASED DONORS    # of Grafts**

demineralized cortical bone \_\_\_\_

demineralized cancellous bone \_\_\_\_

cancellous bone (cubes or morselized) \_\_\_\_

corticocancellous bone \_\_\_\_

proprietary spinal grafts \_\_\_\_

non-proprietary spinal grafts (traditional) (e.g., ICWs, Clowards, fibula rings) \_\_\_\_

osteocondral grafts – **fresh/refrigerated** (i.e., an *allograft* consisting of a section, condyle, or plug of bone with an intact articular surface) \_\_\_\_

osteocondral grafts – **frozen/cryopreserved** (i.e., an *allograft* consisting of a section, condyle, or plug of bone with an intact articular surface) \_\_\_\_

osteoarticular grafts – **fresh/refrigerated** (i.e., a large weight bearing allograft with intact articular surfaces, consisting of a joint with associated soft tissue and bone) \_\_\_\_

osteoarticular grafts – **frozen/cryopreserved** \_\_\_\_ (i.e., a large weight bearing allograft with intact articular surfaces consisting of a joint with associated soft tissue and bone)

meniscus – frozen \_\_\_\_

meniscus – *lyophilized* \_\_\_\_

cartilage (e.g., costal, articular) \_\_\_\_

large segment (articular surface not preserved) (i.e., shaft, proximal large bone, distal large bone) \_\_\_\_

other musculoskeletal grafts from deceased donors; (specify)\_\_\_\_; indicate number for each  
\_\_\_\_

TOTAL musculoskeletal grafts (from deceased donors) \_\_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**

**SOFT TISSUE DISTRIBUTION**

**How many of the following grafts from deceased donors were *distributed* by your *tissue bank*? (Enter 0 if applicable)**

fascia lata \_\_\_\_

ligaments (i.e. patellar) \_\_\_\_

tendons (i.e., Achilles tendons, gracilis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus) \_

rotator cuff \_\_\_\_

pericardium \_\_\_\_

nerves \_\_\_\_

peritoneal membrane \_\_\_\_

dura mater \_\_\_\_

other soft tissue grafts from deceased donors (specify)\_\_\_\_; indicate number for each \_\_\_\_

TOTAL soft tissue grafts (from deceased donors) \_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**

#### **CARDIAC TISSUE AND VASCULAR TISSUE DISTRIBUTION**

**How many of the following *tissues* were *distributed* by your *tissue bank*? (Enter 0 if applicable)**

cardiac tissue # of grafts

*valved conduit* - aortic valves \_\_\_\_

*cryopreserved* (only) \_\_\_\_

acellular / decellularized \_\_\_\_

other (specify) \_\_\_\_

*valved conduit* - pulmonic valves \_\_\_\_

*cryopreserved* (only) \_\_\_\_

acellular / decellularized \_\_\_\_

other (specify) \_\_\_\_

*patch graft* \_\_\_\_

*cryopreserved (only)* \_\_\_\_

*acellular / decellularized* \_\_\_\_\_

*other (specify)* \_\_\_\_

*non-valved conduit - aortic* \_\_\_\_

*cryopreserved (only)* \_\_\_\_

*acellular / decellularized* \_\_\_\_\_

*other (specify)* \_\_\_\_

*non-valved conduit - pulmonic* \_\_\_\_

*cryopreserved (only)* \_\_\_\_

*acellular / decellularized* \_\_\_\_\_

*other (specify)* \_\_\_\_

*aortoiliac graft* \_\_\_\_\_

*cryopreserved (only)* \_\_\_\_

*acellular / decellularized* \_\_\_\_\_

*other (specify)* \_\_\_\_

*other cardiac tissue (specify)* \_\_\_\_\_; indicate number for each \_\_\_\_\_

*TOTAL cardiac tissue distributed* \_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**



Vascular tissue # of grafts

arteries \_\_\_\_

*cryopreserved* (only) \_\_\_\_

acellular / decellularized \_\_\_\_

other (specify) \_\_\_\_

*vein grafts* - saphenous \_\_\_\_

*cryopreserved* (only) \_\_\_\_

acellular / decellularized \_\_\_\_

other (specify) \_\_\_\_

*vein grafts* - iliac \_\_\_\_

*cryopreserved* (only) \_\_\_\_

acellular / decellularized \_\_\_\_

other (specify) \_\_\_\_

other *vascular tissue* (specify) \_\_\_\_ ; indicate number for each \_\_\_\_

TOTAL *vascular tissue distributed* \_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**

**SKIN GRAFT DISTRIBUTION**

**How much *skin* did your *tissue bank* distribute (enter 0 if not applicable)**

square feet \_\_\_\_

number of units/packages \_\_\_\_

**How much of the following categories of skin did your tissue bank distribute? (enter 0 if not applicable. Report both in # of square feet and # of units/packages for each type)**

	# of square feet	# of Units/Packages
fresh	_____	_____
frozen/ <i>cryopreserved</i>	_____	_____
acellular/decellularized	_____	_____
<i>lyophilized</i>	_____	_____
TOTAL	_____	_____

Check here if the information above is actual, tracked information (not an estimate)

**How much skin did your tissue bank distribute to the following? (enter 0 if not applicable. Report both in # of square feet as well as #s of units/packages for each type)**

	# of square feet	# of units/packages
hospitals/burn centers	_____	_____
physicians	_____	_____
<i>tissue distribution intermediaries</i>	_____	_____
other (specify)	_____	_____

Check here if the information above is actual, tracked information (not an estimate)

**How many requests to distribute skin did you receive in [calendar year] that you were not able to fill? (enter 0 if you were able to fill all requests)**

number of requests unable to fill \_\_\_\_

TOTAL number of square feet of skin in requests unable to fill \_\_\_\_

**Indicate for what types of skin you were unable to fill the requests**

- fresh - if checked: Indicate why you were unable to fill these requests: \_\_\_\_\_
- frozen/*cryopreserved* - if checked: Indicate why you were unable to fill these requests:  
\_\_\_\_\_
- acellular/decellularized - if checked: Indicate why you were unable to fill these requests:  
\_\_\_\_\_
- lyophilized* - if checked: Indicate why you were unable to fill these requests: \_\_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**

**TISSUE as a DEVICE - DISTRIBUTION** (i.e., products and combination products requiring PMA or 510k clearance; regulated under the FD&C Act as well as under 21 CFR Part 1271 from Section 361 of the PHSA.)

**List the tissue devices *distributed* by your *tissue bank* and the quantities *distributed***

Tissue Device Name	Quantity (units)
_____	_____
_____	_____
_____	_____
TOTAL	_____

**TISSUE as a BIOLOGICAL PRODUCT - DISTRIBUTION** (i.e., products requiring BLA or IND; regulated under Section 351 of the PHSA and/or the FD&C Act, as well as under 21 CFR Part 1271 from Section 361 of the PHSA)

**List the biological products *distributed* by your *tissue bank* and the quantities *distributed***

Biological Product Name	Quantity (units)
_____	_____
_____	_____
TOTAL	_____

**TISSUE as a DRUG - DISTRIBUTION** (i.e., products requiring IND/NDA; regulated under Section 201 of the FD&C Act, as well as under 21 CFR 1271 from Section 361 of the PHSA)

**List the drug distributed by your tissue bank and the quantities distributed**

Drug Name	Quantity (units)
_____	_____
_____	_____
TOTAL	_____

**DURA MATER DISTRIBUTION**

**How many dura mater grafts were distributed by your tissue bank to the following: (enter 0 if not applicable)**

hospital/medical facilities \_\_\_\_\_

physicians \_\_\_\_\_

tissue distribution intermediaries \_\_\_\_\_

other (specify) \_\_\_\_\_; indicate number for each \_\_\_\_\_

TOTAL dura mater grafts \_\_\_\_\_

**DISTRIBUTION OF TISSUE FROM LIVING DONORS**

**How many of the following tissues from living donors were distributed by your tissue bank? (enter 0 if not applicable)**

amniotic membrane \_\_\_\_\_

chorionic membrane \_\_\_\_\_

amniotic fluid \_\_\_\_\_

Wharton's jelly \_\_\_\_\_

placental/chorionic disc \_\_\_\_\_

umbilical cord tissue \_\_\_\_\_

umbilical veins \_\_\_\_\_

surgical bone \_\_\_\_\_

skin for allogeneic use \_\_\_\_

autologous bone \_\_\_\_

autologous parathyroid \_\_\_\_

other tissue from living donors (specify) \_\_\_\_\_; indicate number for each \_\_\_\_

TOTAL grafts from living donors \_\_\_\_

Check here if the information above is actual, tracked information (not an estimate)

### SUPPLY AVAILABILITY

Check here if you DID NOT have an adequate supply of tissue grafts to meet all the requests that you received in [calendar year]

**Indicated the annual number of grafts of each tissue type that would have been necessary in addition to your available supply to meet the clinical demand:**

Achilles tendons \_\_\_\_

valved conduits

aortic valves \_\_\_\_

- enter size (annulus diameter in mm): \_\_\_\_

pulmonic valves \_\_\_\_

- enter size (annulus diameter in mm): \_\_\_\_

cancellous (bone, chips, crushed, cubed, wedges) \_\_\_\_

cartilage (e.g., costal articular) \_\_\_\_

femoral head \_\_\_\_

frozen whole rib \_\_\_\_

iliac crest wedges (posterior ramps, cervical spacers, tricortical blocks) \_\_\_\_

matchsticks \_\_\_\_

meniscus \_\_\_\_

patella (ligaments, wedges) \_\_\_\_

semitendinosus (tendons) \_\_\_\_

tibialis tendons (anterior and posterior) \_\_\_\_

other (specify) \_\_\_\_\_

Check here if the information above is actual, tracked information (not an estimate)

**IMPLANT REPORTS**

Indicate the percentages (as a range) of *allografts distributed* by your *tissue bank* that had an implant report submitted by the hospitals/surgeons/dentists regarding the *allograft's* use. Indicate if this is an actual, known range or it is an estimate (not tracked)

- 0% – 25%
- 26% – 50%
- 51% – 75 %
- 76% – 100%

Check here if the information above is actual, tracked information (not an estimate)

Check here if your *tissue bank* distributed outside of the U.S. any tissue, tissue as a device, tissue as a biological product, or tissue as a drug that was from donations made in the U.S.

(a) List countries to which *tissues* were *distributed*

**TISSUE FROM DECEASED DONORS**

HCT/Ps regulated solely under Section 361 of the PHSA

musculoskeletal (i.e., bone, cartilage, meniscus, osteoarticular grafts, osteochondral grafts, bone+*cellular tissue*)

\_\_\_\_\_

soft tissue (i.e., fascia lata, ligaments, tendons, pericardium, rotator cuff, nerves)

\_\_\_\_\_

*cardiac tissue* \_\_\_\_\_

*vascular tissue* \_\_\_\_\_

*skin-derived grafts* \_\_\_\_\_

*dura mater* \_\_\_\_\_

tissue as a device \_\_\_\_\_

- specify: \_\_\_\_\_

tissue as a biological product \_\_\_\_\_

- specify: \_\_\_\_\_

tissue as a drug \_\_\_\_\_

- specify: \_\_\_\_\_

### TISSUE FROM LIVING DONORS

#### HCT/Ps regulated solely under Section 361 of the PHSA

amniotic membrane \_\_\_\_\_

chorionic membrane \_\_\_\_\_

amniotic fluid \_\_\_\_\_

Wharton's jelly \_\_\_\_\_

placental/chorionic disc \_\_\_\_\_

umbilical cord tissue \_\_\_\_\_

umbilical vein \_\_\_\_\_

*surgical bone* \_\_\_\_\_

*skin for allogeneic use* \_\_\_\_\_

*autologous bone* \_\_\_\_\_

*autologous parathyroid* \_\_\_\_\_

other *tissue from living donors* (specify) \_\_\_\_\_; countries: \_\_\_\_\_

tissue as a device \_\_\_\_\_

- specify: \_\_\_\_\_

tissue as a biological product \_\_\_\_\_

- specify: \_\_\_\_\_

tissue as a drug \_\_\_\_\_

- specify: \_\_\_\_\_

(b) Considering all *distribution of tissue*, estimate the percentage of overall *distribution* that occurs to destinations outside of the United States: \_\_\_\_\_

**Check here if the information above is actual, tracked information (not an estimate)**