Form Approved

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**THE NATIONAL TISSUE RECOVERY**

**THROUGH UTILIZATION SURVEY**

**SECTION 6 – Tissue Storage**

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).

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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 30 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

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| **Tissue Storage** |
| **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, include numbers only for your main facility and your *satellite facilities* (if applicable). The information you are reporting is for the following physical locations(s) by name, city and state:**1. name, city, state

 B. name, city, state*(need capability for multiple lines/entries)* |
| **Which of the following UNPROCESSED *tissues* did your *tissue bank* *store*:** □ tissue from deceased donors□ musculoskeletal (i.e., bone, cartilage, osteoarticular grafts/joints)□ soft tissue (i.e. fascia lata, ligaments, tendons, pericardium, nerves, peritoneal membrane, adipose)□ *cardiac tissue*□ *vascular tissue*□ *skin*□ *cellular tissue*□ *dura mater*□ other tissue from deceased donors (specify)\_\_\_\_ □ tissue from *living donors*:□ *birth tissue* □ placenta□ amniotic fluid□ Wharton’s jelly□ umbilical cord tissue□ umbilical vein□ *surgical bone*□ *skin* for *allogeneic* use□ *autologous* bone□ *autologous* parathyroid□ other *autologous* (specify) \_\_\_\_\_\_\_\_\_\_□ other tissue from *living donors* (specify)\_\_\_\_\_\_\_\_\_\_   |
| **Which of the following PROCESSED tissues did your *tissue bank store*:**□ TISSUES FROM DECEASED DONORSHCT/Ps regulated solely under Section 361 of the PHSA□ musculoskeletal□ bone □ cartilage (e.g., costal, articular) □ 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)□ soft tissue□ fascia lata□ ligaments (i.e. patellar)□ tendons (e.g., Achilles, gracillis, anterior/posterior tibialis, semitendinosus, flexors/extensors, peroneus longus) \_\_\_□ pericardium \_\_\_\_\_□ nerves \_\_\_\_\_□ peritoneal membrane\_\_\_\_ □ adipose \_\_\_\_\_ □ *cardiac tissue*□ *valved conduits* \_\_\_\_\_□ *non-valved conduits* \_\_\_\_\_□ *patch grafts* \_\_\_\_\_□ *aortoiliac grafts* \_\_\_\_\_□ *vascular tissue*□ arteries□ *vein grafts*□ *skin* □ fresh□ *cryopreserved* □ *lyophilized* □ dehydrated□ dessicated □ *cellular tissue* □ *dura mater*□ other PROCESSED tissue *stored* 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□ *birth tissue* \_\_\_\_\_□ amniotic membrane (only)□ chorionic membrane (only)□ amniotic+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 PROCESSED tissue *stored* 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 if you *store* any tissue recently *recovered* or *processed* by any of the following methods:** □ refrigerated (> 0°C to 10°C)□ frozen – short term (-20°C to 40°C) □ frozen – long term (< -40°C)□ *cryopreserved* (< -100°C) □ ambient□ controlled room temperature (e.g., 15°C to 30°C)□ other method of *storage* (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |