Form Approved

 OMB No. 0990-

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**THE NATIONAL TISSUE RECOVERY**

**THROUGH UTILIZATION SURVEY**

**Section 2 – Referrals, Authorization, Informed Consent**

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).

xxxxx

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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| **Referrals, Authorization, Informed Consent** |
| **The survey provides definitions for specific donors and tissue types. To facilitate accurate totals, count donations using the descriptions provided. Where terms are *italicized*, use the definitions found at AATB Standard A2.000 DEFINITIONS OF TERMS. Some terms and/or definitions are new and some have been revised. Refer to the NTRUS Definitions of Terms document provided with this survey.** **Except where noted, all donations are for *transplantation*.** **Do NOT include ocular-only donors in this survey.** **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
2. name, city, state

*(need capability for multiple lines/entries)* |
| **DECEASED DONATION****Enter the total number of donor referrals by source (enter counts, not percentages).** Consider the “source” to be the facility or person reporting the death. **Enter 0 at a selection if not applicable.**hospitals \_\_\_\_\_medical examiners/coroners \_\_\_\_\_\_law enforcement \_\_\_\_\_\_funeral home \_\_\_\_\_\_extended care facilities/Nursing homes (includes hospice/donor initiated) \_\_\_\_\_\_first responders (paramedics/EMS) \_\_\_\_\_\_donor family (home)other source (specify) \_\_\_\_\_\_; indicate number \_\_\_\_\_\_ TOTAL \_\_\_\_\_\_**LIVING DONATION****Enter the total number of donor referrals by source (enter counts, not percentages).** Consider the “source” to be the facility or person making the referral. **Enter 0 at a selection if not applicable**hospital surgical department \_\_\_\_\_hospital delivery/birth centers  \_\_\_\_\_\_\_freestanding birth centers  (not at a hospital) \_\_\_\_\_\_\_physicians \_\_\_\_\_family/donor initiated (home) \_\_\_\_\_\_other source (specify) \_\_\_\_\_\_; indicate number \_\_\_\_\_\_ |
| **DECEASED DONATION**How many requests for *authorization* did your *tissue bank* make? \_\_\_\_\_How many *authorizations* did your *tissue bank* obtain in total? \_\_\_\_\_\_Enter the number of *authorizations* that came from First Person/Donor Designation/*donor registry* \_\_\_\_\_\_Enter the number of *authorizations* that came from an “intent registry” (a registry but not legally valid) \_\_\_\_\_\_Enter the number of *authorizations* from an *authorizing person* or *persons* \_\_\_\_\_\_How many requests for *authorization* were denied? \_\_\_\_\_\_Enter the number when an *authorizing person* was not available \_\_\_\_\_\_How many *authorizations* were obtained but *tissue* was not *recovered*? \_\_\_\_\_\_**LIVING DONATION**How many requests for *informed consent* did your *tissue bank* make? \_\_\_\_\_How many *informed consents* did your *tissue bank* obtain in total? \_\_\_\_\_\_How many requests for *informed consent* were denied? \_\_\_\_\_\_How many *informed consents* were obtained but *tissue* was not *acquired*? \_\_\_\_\_\_ |
| **DECEASED DONATION****Indicate the number of *authorizations* for donation that were requested by the following:**Report the number by a **trained requestor** (An individual deemed competent by the OPO or agency to seek *authorization* for donation):requestor at *tissue bank/*OPO who only handles tissue donation *authorization* \_\_\_\_\_\_hospital personnel \_\_\_\_\_\_requestor at *tissue bank* /OPO who also handles organ donation *authorizations* \_\_\_\_\_\_designated screening/*authorization* service \_\_\_\_\_\_medical examiner/coroner \_\_\_\_\_\_\_other *authorizations* were requested by whom? \_\_\_\_\_\_; indicate number \_\_\_\_\_\_ □ Check if this information is not obtainable Report the number by a **non-trained requestor**:hospital personnel \_\_\_\_\_\_medical Examiner/Coroner \_\_\_\_\_\_\_other *authorizations* were requested by whom?\_\_\_\_\_\_; indicate number\_\_\_\_\_\_□ Check if this information is not obtainable **LIVING DONATION****Indicate the number of *informed consents* for donation that were requested by the following:**requestor at *tissue bank/*OPO who only handles tissue donation *authorization* \_\_\_\_\_\_hospital personnel \_\_\_\_\_\_hospital delivery/birth center personnel \_\_\_\_\_freestanding birth center personnel (not at a hospital) \_\_\_\_\_physicians \_\_\_\_\_other *informed consents* were requested by whom?\_\_\_\_\_\_; indicate number\_\_\_\_\_\_□ Check if this information is not obtainable  |
| **DECEASED DONATION****Does your *authorization* process include a request regarding international distribution of the gift?** □ Yes□ No**Does your *authorization* process include a request regarding for-profit or not-for-profit involvement or restrictions on the gift?** □ Yes□ No**LIVING DONATION****Does your *informed consent* process include a request regarding international distribution of the gift?** □ Yes□ No**Does your *informed consent* process include a request regarding for-profit or not-for-profit involvement or restrictions on the gift?** □ Yes□ No |
| **DECEASED DONATION**(Note: the following information may be obtainable from the organization contracted to handle your donor referrals.)**Indicate the number of ALL referrals determined ineligible during screening (prior to going on site for *recovery*)** \_\_\_\_\_**Indicate the number of ALL referrals determined ineligible during screening (prior to going on site for *recovery*) for the following reasons:**age \_\_\_\_\_\_medical history \_\_\_\_\_\_behavioral risk history \_\_\_\_\_travel/residence historytime restrictions \_\_\_\_\_infectious disease testing \_\_\_\_\_*plasma dilution* \_\_\_\_\_\_trauma \_\_\_\_\_medical examiner/coroner restrictions \_\_\_\_\_funeral home restrictions (i.e., body embalmed) \_\_\_\_\_\_other ineligible referrals during screening (specify) \_\_\_\_\_; indicate number \_\_\_\_\_\_\_Choose only one:□ The reasons were obtainable for **all** referrals. □ The reasons were obtainable for **some** referrals. □ The reasons were **not** obtainable.**LIVING DONATION**(Note: the following information may be obtainable from the organization contracted to handle your donor referrals.)**Indicate the number of ALL referrals determined ineligible during screening (prior to *recovery/acquisition*)** \_\_\_\_\_**Indicate the number of ALL referrals determined ineligible during screening (prior to *recovery/acquisition*) for the following reasons:**medical history \_\_\_\_\_\_behavioral risk history \_\_\_\_\_travel/residence history\_\_\_\_\_infectious disease testing \_\_\_\_\_*plasma dilution* \_\_\_\_\_\_other ineligible referrals during screening (specify) \_\_\_\_\_; indicate number \_\_\_\_\_\_\_Choose only one:□ The reasons were obtainable for **all** referrals. □ The reasons were obtainable for **some** referrals. □ The reasons were **not** obtainable. |
| **DECEASED DONATION****Estimate the percentage of *authorizations* that provided use of the gift for research:\_\_\_\_\_\_%****LIVING DONATION****Estimate the percentage of *informed consents* that provided use of the gift for research:\_\_\_\_\_\_%** |