



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

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 location(s) by name, city and state:

A. name, city, state

B. 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 history _____

time 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: _____%