Form Approved
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THE NATIONAL TISSUE RECOVERY THROUGH UTILIZATION SURVEY

SECTION 7 – Communicable Disease Testing & Adverse Outcome Reports

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.

Communicable Disease Testing & Adverse Outcome Reports

There are three options for answering questions about communicable disease testing of donors. Check which one applies to your *tissue bank*:

□ Reporting totals only for donor communicable disease testing that our *tissue bank* DIRECTLY ordered. This means our tissue bank supplied the sample to the testing laboratory under our own contract and results may have been shared with others entities that received tissue (this is preferred); or

□ Reporting totals only for donor communicable disease testing ordered by others through a contract or agreement with a tissue recovery program. This means our tissue bank did not directly order the tests (this is acceptable);

□ Reporting totals for donor communicable disease testing that uses a combination of the two selections above (this is acceptable but not preferred because it could lead to double reporting); or

□ Our *tissue bank* is not involved in ordering communicable disease testing. (skip to Adverse Outcome Reports section)

List all test(s) that your *tissue bank* relies upon to confirm a repeat-reactive syphilis screening test?

□ VDRL

□ FTA-ABS

□ MHA-TP

□ Olympus PK TP System

□ ASI TPHA Test

□ CAPTIA TM Syphilis (*T. Pallidum*) - G

□ TPHA Screen

□ Other____ Specify: _____

□ N/A – confirmatory testing is not performed

DECEASED DONORS

Provide the following donor test counts and results for [calendar year]:

Assay	**Screening Test Results**			**Confirmatory/Supplemental Test Results**		
	# Donors Tested	# Donors Nonreactive/ Negative	# Donors Repeatedly Reactive/Positive or Indeterminate	# Donors Negative	# Donors Positive	# Donors Indeterminate
HBsAg						
anti-HBcAb (total)						
anti-HBcAb (IgM)						
anti-HCV						
anti-HIV-1/2						
anti-HIV-2						
Anti-HTLV I/II						
Treponemal						
Non-treponemal						
NAT (HIV-1)						
NAT (HIV-2)						
NAT (HCV)						
NAT (HIV-1/HCV)						
NAT (HBV)						
NAT (HIV-1/HBV/HCV)						
NAT (HIV-1/HIV-2/HBV/HCV)						
NAT (WNV)						
anti-*T.cruzi*						
anti-CMV						

LIVING DONORS

Provide the following donor test counts and results for [calendar year]:

Assay	**Screening Test Results**			**Confirmatory/Supplemental Test Results**		
	# Donors Tested	# Donors Nonreactive/ Negative	# Donors Repeatedly Reactive/Positive or Indeterminate	# Donors Negative	# Donors Positive	# Donors Indeterminate
HBsAg						
anti-HBcAb (total)						
anti-HBcAb (IgM)						
anti-HCV						
anti-HIV-1/2						
anti-HIV-2						
Anti-HTLV I/II						
Treponemal						
Non-treponemal						
NAT (HIV-1)						
NAT (HIV-2)						
NAT (HCV)						
NAT (HIV-1/HCV)						
NAT (HBV)						
NAT (HIV-1/HBV/HCV)						
NAT (HIV-1/HIV-2/HBV/HCV)						
NAT (WNV)						
anti-*T.cruzi*						
anti-CMV						

Adverse Outcome Reports

The following information only considers tissue products regulated solely under Section 361 of the PHSA (i.e., conventional tissue).

Indicate how many reports your *tissue bank* received of suspected transmission of disease or of graft failure following transplantation and information regarding reporting to others. Also, provide assessment/outcome information for reports received.

Reports Received		**Reported to Others by Tissue Bank**			**Report Assessment/Outcome**			
	Total # of Reports	# Reported to FDA	# Reported to international health authorities	# Reported to local/state health authorities	Likely/ Probably caused by the graft*	Proven as caused by the graft*	Not otherwise specified*	Resulted in recipient death
Bacterial								
Viral								
Fungal								
Malignancy								
Other infection								
Graft Failure (only)								

* Use these definitions:

Likely/Probably caused by the graft =
(EUSTITE definition) When the evidence is clearly in favor of attributing the adverse reaction to the quality/safety of tissues/cells.
(NOTIFY definition for "Probable") Strong evidence suggesting but not proving a disease transmission.

Proven as caused by the graft =
(EUSTITE definition for "definite/certain") When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the quality/safety of tissues/cells.
(NOTIFY definition for "Proven") Clear evidence of the same infection disease in the donor and at least one of the recipients.

Not otherwise specified =
Does not meet definition of "**Likely/Probably"** or **"Proven"**

The following information only considers tissue products regulated as tissue as a device, tissue as a drug, or tissue as a biologic.

Reports Received		**Reported to Others by Tissue Bank**			**Report Assessment/Outcome**			
	Total # of Reports	# Reported to FDA	# Reported to international health authorities	# Reported to local/state health authorities	Likely/ Probably caused by the graft*	Proven as caused by the graft*	Not otherwise specified*	Resulted in recipient death or serious injury
Bacterial								
Viral								
Fungal								
Malignancy								
Other								
Graft malfunction (only) (e.g., failure of expected pharmacological action								