Supporting Statement A for
National Tissue Recovery through Utilization Survey (NTRUS)

OMB Number: **TBD**

June 2017

Contact Information:

Debbie Seem, RN, MPH
Advisor/Program Director, Tissue Initiatives
Office of HIV/AIDS & Infectious Disease Policy
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
330 C Street, SW, Suite L100
Washington, DC 20024
202-795-7619
debbie.seem@hhs.gov

PART A – JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Policy advice provided by the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) to the HHS Secretary and Assistant Secretary for Health is used to direct departmental efforts to address transfusion and transplantation issues, such as emergency preparedness and infectious disease transmission related to donated human tissue. The advice provided is partly dependent on analysis of relevant information, such as tissue collection (recovery) through utilizations data. These data, last collected in 2007 by the American Association of Tissue Banks (AATB) with private funding, continue to be cited in publications and referenced in ACBTSA meeting discussions. However, the data likely does not reflect current tissue activity and practices. Distribution of tissue grafts surpasses 2 million per year, but it remains unknown whether and to what extent reserve inventories exist or if surges in production of tissue grafts can be accomplished in time of national need. Similarly, tissue recovered from one deceased donor can be sent to multiple tissue processors with more than 50 grafts produced. Rapid identification and quarantine of tissue is critical when a tissue recipient is suspected to have a donor-derived infection; however current information on the quantity of tissue distributed internationally and U.S. tissue distribution patterns is unknown. To that end, under the authority granted in Section 301 of the Public Health Service Act (42 U.S.C. 241) authorizing the conduct of research, the National Tissue Collection through Utilization Survey (NTRUS) would collect current data needed to better inform public health strategic and regulatory agendas on tissue safety, supply and demand.

2. Purpose and Use of Information Collection

The objective of the survey is to generate information on national tissue recovery through utilization activities of donated human tissue that occurred in calendar years 2012 and 2015, and compare metrics across the two data collection periods, including selected metrics that cover the same activities from CY 2007. Meaningful quantitative comparisons of data and monitoring of trends will use a survey instrument and data collection and analysis methods that are very similar to the initial 2007 AATB survey conducted on tissue establishment practices for 2007.

This survey is a census of tissue banks, located within the 50 states and District of Columbia, that engage in the screening, recovery, testing, processing, storage, and/or distribution of human tissue. The approximate 110 tissue banks are registered with FDA and the tissue type must meet all the criteria under 21 CFR 1271.10(a) and, therefore, are solely regulated under section 361 of the Public Health Service Act (e.g., minimally manipulate; not combined with another article , except for water, crystalloids, or a sterilizing, preserving, or storage agent.). Examples of tissue types that will be addressed include bone, cartilage, dura mater, fascia, heart valves, ligament, pericardium, skin, tendon, vascular graft (veins, arteries), and birth tissue. Ocular tissue, reproductive tissue, peripheral and umbilical cord blood stem cells, or somatic cell therapy products that are also solely regulated under section 361 of the PHS will not addressed.

The NTRUS provides a unique opportunity for federal agencies, including FDA which regulates tissue establishments, to obtain data on tissue donors, including screening and testing, and tissue recovery and distribution. HHS agencies receive requests from entities such as Congress, the media, and other U.S. and foreign regulatory agencies asking for the annual distribution of U.S. tissues by U.S. tissue establishments. Since FDA has no mechanism for collecting or monitoring tissue distribution volume, data from the 2007 AATB survey continues to be referenced. Data on tissue distribution provide an estimated denominator for assessing the risk of various types of tissues in the context of adverse reaction reports submitted to FDA. Tissue tracking and traceability have been high profile issues for tissue products. The NTRUS will provide data on return of tissue implant cards/reports to tissue establishments. Such data obtained by the NTRUS may aid in determining whether additional efforts are needed to improve the return of such reports by tissue consignees, which is currently voluntary. Also, as the U.S. has increasingly become a supplier of tissues for other countries, it is important to be aware of which tissues are distributed internationally and in what volume. Such data are helpful to HHS agencies that work with international counterparts on regulatory issues regarding the safety of human tissues. Information on the general quantity of skin recovered and processed is useful to OASH and ASPR/BARDA for preparedness planning in the event of a large-scale disaster involving burn patients. The NTRUS data, particularly if such a survey can be conducted periodically, would provide data on changing trends in donor screening and testing and tissue manufacturing, distribution, and utilization that may help determine where regulatory changes may be needed. Survey data will also be of practical use to the tissue industry to advance quality standards and procedures.

Each question in the proposed survey relates to the analysis objectives detailed in Section 16 and lists the questions by survey domains. The seven general categories of information to be collected are:

- Tissue bank activities, tissue types handled, and inspections
- Referrals, authorizations, and informed consent
- Tissue recovery and acquisition
- Tissue processing
- Tissue storage
- Tissue distribution
- Communicable disease testing and adverse outcome reports

3. Use of Improved Information Technology and Burden Reduction

The survey will be provided electronically to approximately 110 tissue banks via an approved unique URL. Each tissue bank will access the survey through an email invitation link. Each of the seven survey domains may be completed directly into a computer or can be printed allowing the responding tissue bank to gather the information offline and then submit the response to that section online in one sitting. Using the unique link in the email invitation, respondents will be able to return to their ‘task list’ to complete subsequent sections, as needed.

4. Efforts to Identify Duplication and Use of Similar Information

Current data is maintained only by individual tissue banks. In communications with the Division of Human Tissue at FDA/CBER and the AATB, national tissue collection through utilization data was last gathered and reported for CY 2007. Since 2007, the field of tissue transplantation has experienced considerable changes, which this survey should help to inform.

- Investments in research and development have increased the types of grafts available for transplantation and the quantities produced and distributed.
- The number of individuals signing up on state registries to be tissue donors, and the degree to which tissue banks accept first person consent for deceased donors listed on these registries.
- New communicable diseases tests to screen donors have been introduced since 2007's survey, and some previous tests are no longer used;
- Business practices by some tissue processors appear to be leaning toward having decreased inventory on the shelf, and in certain situations could have a devastating effect on patients, such as for burn victims in large scale disaster if skin for wound coverage is in short supply.
- The expansion of tissue banks that acquire conventional tissues from living donors, particularly birth tissue
- Current information of the quantity and types of tissue grafts distributed nationally and internationally are needed to help inform complex issues, such as tissue tracking and quarantine, where a donor graft is the suspected source of infection in a tissue recipient.

5. Impact on Small Businesses or Other Small Entities

Small businesses or entities are not involved. All respondents are tissue banks of which some serve several states, one state, partial states, or parts of several states. When tissue banks click on the link in their email invite, they will be taken into the survey and will see a 'task list' of only the sections they are required to complete. All tissue banks will complete the first section and between one and six of the remaining survey sections, depending on the services provided (e.g., tissue recovery, tissue processing, tissue distribution). In general, small tissue banks provide fewer services than large tissue banks and, therefore, would complete fewer sections of the survey. And, due to specialization where limited tissue types are handled, fewer survey questions will apply to a small tissue bank. The survey will include a glossary of definitions. In addition, the tissue banks will have access to toll-free telephone support for questions related to the survey.

6. Consequences of Collecting Information Less Frequently

Each tissue bank is being asked to provide their data only once.

7. Special Circumstances Relating to Guidelines of 5CFR 1320.5

This request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register Notice was published in the *Federal Register* on September 7, 2016, vol. 81, No. 173; pp. 61703 (see attachment). There were no public comments.

Subject matter experts from various tissue banks were sought to review and update, as appropriate each section of the 2007 AATB survey instrument. The following representatives, identified with the tissue bank they represent, met with colleagues in their respective work groups via conference call and GoToMeeting until each section was completed.

Survey section	Subject matter experts	Tissue banks represented
Tissue bank activities, tissue types handled, and inspections	Sandra Bausback-Aballo, Michael Plew, Tim Maye, Kelly Snyder, Rebeccah Brown, Joel Osborne, Rochelle Maney, Becky Clasper, Sue Sutton-Jones	LifeCell, LifeNet Health, DCI Donor Services, MiMedx, Musculoskeletal Transplant Foundation, CryoLife, RTI Surgical
Referrals, authorization, and informed consent	Sandra Bausback-Aballo, Pete Sykes, David Marshman, Jennifer Towers, Kimber Ramos, Stephanie Cozby, Mark Rogers, Tami James, Flo Rosenberg, Allison Rickman, Alan Taylor, Jacob Chrzanowski, Julie Zabloski, Gary Harris	LifeCell, LifeNet Health, DCI Donor Services, Sierra Donor Services, New Mexico Donor Services, MiMedx, Aziyo Biologics, Musculoskeletal Transplant Foundation, CryoLife, Donor Network of Arizona, LifeSource, LiveOnNY
Tissue recovery and acquisition	Mark Van Allman, Earl Jones, Rebeccah Brown, Tommy Churchill, Mike Real, Allyson May, Alan Taylor, Rhiannon Knueven, Julie Zabloski, Gary Harris	LifeNet Health, Tennessee Donor Services, MiMedx, LifeLink TB, Musculoskeletal Transplant Foundation, CryoLife, Donor Network of Arizona, LifeSource, LiveOnNY
Tissue processing	Mike Poole, Heather Germany, Pete Jenkins, Mark Rogers, Erica Elchin, Brad Bassler, Adrienne Pryor, Joe Yaccarino, Rochelle Maney, Becky Clasper	LifeNet Health, LifeNet Health, DCI Donor Services, MiMedx, Aziyo Biologics, LifeLink Tissue Bank, Medtronic/Osteotech, Musculoskeletal Transplant Foundation, CryoLife
Tissue storage	Mike Poole, Heather Germany, Carrie Crocker, Rebeccah Brown, Joe Yaccarino, Rochelle Maney, Becky Clasper	LifeNet Health, DCI Donor Services, MiMedx, Musculoskeletal Transplant Foundation, CryoLife
Tissue distribution	Mike Poole, Heather Germany, Marie Drab, Mark Rogers, Miriam	LifeNet Health, DCI Donor Services, MiMedx, Medtronic/Osteotech,

	Estrano, Joe Yaccarino, Rochelle Maney, Becky Clasper	Musculoskeletal Transplant Foundation, CryoLife
Communicable disease testing and adverse outcome reports	Sandra Bausback-Aballo, Kathy Pearson, Kelly Snyder, Rebeccah Brown, Mike Real, Rochelle Maney, Becky Clasper	LifeCell, LifeNet Health, DCI Donor Services, MiMedx, Musculoskeletal Transplant Foundation, CryoLife

Aziyo Biologics, 800-922-3100
Erica Elchin, VP Technical Services/Quality, eelchin@aziyo.com
Tami James, Project Manager/QA, tjames@aziyo.com

CryoLife, 800-438-8285
Becky Clasper, Senior Auditor/CAPA Coordinator, clasper.becky@cryolife.com
Rochelle Maney, Director, Regulatory Compliance, maney.rochelle@cryolife.com
Allyson May, Donor Services Account Manager – West, may.allyson@cryolife.com
Allison Rickman, Sr Donor Services Account Manager – East,
rickman.allison@cryolife.com

DCI Donor Services, 888-234-4399
Carrie Crocker, Sr Director – GTP Quality System, ccrocker@dcids.org
Marie Drab, Director of Client Services, mdrab@dcids.org
Pete Jenkins, Sr Director of Operations, pjenkins@dcids.org
Kelly Snyder, Executive Director – Tissue Bank, ksnyder@dcids.org
Jennifer Towers, Quality Manager, jtowers@dcids.org

Donor Network of Arizona, 800-943-6667
Jacob Chrzanowski, Referral & Donor Services Supervisor, jacob@dnaz.org
Rhiannon Knueven, Tissue Recovery Manager, rhiannon@dnaz.org
Alan Taylor, Tissue Services Director, alan@dnaz.org

LifeCell, 800-717-7427
Sandra Bausback-Aballo, Director, Global Clinical Safety, sbausback@acelity.com

LifeLink Tissue Bank, 800-683-2400
Brad Bassler, VP Operations, brad.bassler@lifelinkfound.org
Tommy Churchill, Director, Tissue Recovery Services,
tommy.churchill@lifelinkfound.org

LifeNet Health, 800-847-7831
Heather Germany, VP Production & Statistics, heather_germany@lifenethealth.org
Tim Maye, VP Quality Systems, tim_maye@lifenethealth.org
David Marshman, Director, OPO Quality Systems, david_marshman@lifenethealth.org
Kathy Pearson, VP Tissue Quality/Risk Management, kathy_pearson@lifenethealth.org
Michael Plew, VP Quality & Regulatory Compliance, Michael_plew@lifenethealth.org

Mike Poole, VP Production & Statistics, mike_poole@lifenethealth.org
Pete Sykes, Director of Donor Center, pete_sykes@lifenethealth.org
Mark Van Allman, National Director of Tissue Recovery,
mark_vanallman@lifenethealth.org

LifeSource, 888-536-6283
Julie Zabloski, Director of Donor Services Center and Tissue Services, jzabloski@life-source.org

LiveOnNY, 646-291-4444
Gary Harris, Director of Donor Center & Tissue Services, gharris@liveonny.org

Medtronic/Osteotech, 800-542-2045
Miriam Estrano, Compliance/Audit Manager, miriam.estrano@medtronic.com
Adrienne Pryor, Sr Manufacturing Manager, adrienne.pryor@medtronic.com

MiMedx, 404-461-9265
Rebeccah Brown, VP Product Development & Regulatory Affairs, rbrown@mimedx.com
Mark Rogers, VP Quality Assurance and Regulatory Affairs, mrogers@mimedx.com

Musculoskeletal Transplant Foundation, 800-946-9008
Joel Osborne, VP Regulatory Affairs, joel_osborne@mtf.org
Mike Real, VP- Procurement, Mike_Real@mtf.org
Flo Rosenberg, Director - Donor Screening & Coordination, Flo_Rosenberg@mtf.org
Joe Yaccarino, Executive VP – Operations, Joe_Yaccarino@mtf.org

New Mexico Donor Services, 505-843-7672
Stephanie Cozby, Sr. Director of Quality, SCozby@dcids.org

RTI Surgical, 877-343-6832
Sue Sutton-Jones, VP Regulatory Affairs/Quality Assurance, ssutton-jones@rtix.com

Sierra Donor Services, 916-569-0200
Kimber Ramos, Sr Director of Quality & Compliance, kramos@dcids.org

Tennessee Donor Services, 352-359-7025
Earl Jones, Sr Director of Tissue Services, ejones@dcids.org

The group of experts expanded the survey to capture data regarding living donors of birth tissue. Although steps were taken to improve the wording in the section on communicable disease testing, it was deemed difficult to collect such test results without experiencing some duplicate reporting across donors whose tissue types were shared with more than one tissue bank that processes. Depending on tissue bank data collection systems, some survey data will be estimates.

DHHS
The following federal employees were consulted for the initial and final review of the survey instrument.

Matthew Kuehnert, MD (no longer with CDC)
Director, Office of Blood, Organ and other Tissue Safety
National Center for Emerging Zoonotic and Infectious Diseases, CDC
mgk8@cdc.gov

Laura St. Martin, MD (no longer with this office)
Division of Human Tissue
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research, FDA

Michelle McClure, PhD
Division of Human Tissue
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research, FDA
Michelle.Mcclure@fda.hhs.gov

Craig Zinderman, MD, MPH
Acting Deputy Director, Division of Epidemiology
Center for Biologics Evaluation and Research, FDA
Craig.Zinderman@fda.hhs.gov

9. Explanation of Any Payment or Gifts to Respondents
Responding institutions will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents
The Privacy Act does not apply to the proposed data collection since respondents are not human subjects, but tissue banks. This project is exempt from review and approval of an IRB as donor data are provided in aggregate form from participating tissue banks and no donor identifiers are collected.

11. Justification of Sensitive Questions
This data collection does not include questions of a sensitive nature.

12. Estimates of Annualized Hour and Cost Burden
The burden for the NTRUS is summarized in the table below. Each tissue bank that is asked to complete the survey, or section(s) of the survey is considered to be a respondent. All participating tissue banks complete the first section and between one and six of the remaining survey sections, depending on the services provided. The number of eligible respondents is about 110. The hour-burden estimates are based on information provided by tissue bank representatives, listed in Section 8 of this document, during meetings to address the survey instrument sections.

12A. Estimated Annualized Burden Hours

Type of Respondent	**Survey Section**	**No. of Respondents**	**No. Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
(1) All tissue banks	Tissue bank activities, tissue types handled, and inspections	110	1	10/60	18.33
(2) Tissue banks that handle referrals; (3) Recover/ acquire tissue	Referrals, authorization, and informed consent; Tissue recovery and acquisition	80	1	1	80
(4) Tissue banks that process tissue	Tissue processing	35	1	1	35
(5) Tissue banks that store tissue	Tissue storage	65	1	20/60	21.67
(6) Tissue banks that distribute tissue	Tissue distribution	58	1	30/60	29
(7) Tissue banks that have donor infectious disease testing performed and may handle adverse outcome reports	Communicable disease testing and adverse outcome reports	35	1	1	35
Total					219

12B. Estimated Annualized Burden Costs

Respondents are best characterized as database administrators per the U.S. Bureau of Labor Statistics, with average hourly rates of $40.00. The annualized cost to these respondents is estimated at $8760.00 based on $40.00 per hour with only one data collection cycle in total to occur within a one year timeframe upon OMB approval.

Type of Respondent	**Survey Section**	**No. of Respondents**	**No. Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**	**Wages***	**Total Respondent Cost**
All tissue banks	Tissue bank activities, tissue types handled, and inspections	110	1	10/60	18.33	$40.00	$733.20
Tissue banks that handle referrals; Recover/ acquire tissue	Referrals, authorization, and informed consent; Tissue recovery and acquisition	80	1	1	80	$40.00	$3200.00
Tissue banks that process tissue	Tissue processing	35	1	1	35	$40.00	$1400.00
Tissue banks that store tissue	Tissue storage	65	1	20/60	21.67	$40.00	$866.80
Tissue banks that distribute tissue	Tissue distribution	58	1	30/60	29	$40.00	$1160.00
Tissue banks that have donor infectious disease testing performed and may handle adverse outcome reports	Communicable disease testing and adverse outcome reports	35	1	1	35	$40.00	$1400.00
Total					219		$8760.00

*http://www.bls.gov/ooh/computer-and-information-technology/database-administrators.htm

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital costs or costs to maintain capital associated with this information collection.

14. Annualized Cost to the Federal Government

All survey operations, including survey development, data collection and validation, analysis, and reporting are contracted to the AATB by the government. The total cost of this fixed-price contract is $105,414. Personnel costs of federal employees involved in oversight and analysis are estimated at $26,000. The annualized cost to the federal government is estimated to be $131,414.

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Activity	Time Schedule
Receive OMB approval	Pending
End data collection	16 weeks following OMB approval
Complete data validation and creation of dataset	8 weeks after data collection completed
Receive final comprehensive report	12 weeks after dataset approved
Publish report	2 weeks after receipt of final report

The survey will be distributed electronically to approximately 110 U.S. tissue banks, encompassing all facilities that are within the scope of this survey. Statistical methods to analyze the data will be limited to frequency calculations. Aggregate results for each question will be presented, including response rates and categorization by group or type, as appropriate.

Selected examples for the types of analyses proposed include:

- Number of potential donors determined ineligible by reason
- Number of potential donors tested and number of positive test results by infectious disease marker types
- Number of tissue donors
- Average number of tissue grafts per deceased donor
- Number of tissue grafts processed by graft type and treatment method (e.g., antibiotics, washes, radiation)
- Number of tissue grafts distributed by graft type (e.g., fresh osteoarticular joints; heart valves; skin, including quantity in square feet; bone; tendons; arteries; veins)
- Number of tissue graft requests unable to fill by graft type
- Number of reports received of suspected transmissions from transplanted tissue by disease category (viral, bacterial, fungal, malignancy, other infection); and of these reports, the number determined to be probable or proven
- Percent of overall graft distribution to destinations outside the U.S.

- Comparisons between survey results for CYs 2012 and 2015, and selected survey results from CY 2007.

A comprehensive report of survey findings will be posted on the HHS Office of HIV/AIDS and Infectious Diseases, Blood and Tissue Safety and Availability, website accessible at https://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/index.html.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate.
The OMB expiration date will be displayed on the data collection form.

A18. Exceptions to Certification of Paperwork Reduction Act Submissions
There are no exceptions to the certification.