

SUPPORTING STATEMENT

Data Collection for Organ Procurement and Transplantation Network ZIKA Virus Pilot Project

OMB Control No. 0906-XXXX-New

A. Justification

1. Circumstances of Information Collection

This is a request for Office of Management and Budget (OMB) approval for a data collection form for use as part of a pilot project regarding Zika virus (ZIKV) screening for deceased potential organ donors. Participating Organ Procurement Organizations (OPOs) will be asked to submit testing results for deceased potential donors who may have been exposed to ZIKV.

OPOs will be selected for participation in the study based on geographic locations where Zika virus has been reported or predicted to emerge, including large urban areas,

Section 372 of the Public Health Service (PHS) Act (42 USC 274) requires that the Secretary of Health and Human Services, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN must assist organ procurement organizations (OPOs) in the equitable distribution of organs among transplant patients nationwide and adopt and use standards of quality for the acquisition and transportation of donated organs. In accordance with Section 372(b)(2)(I) of the PHS Act (42 U.S.C. § 274 (b)(2)(I)), the OPTN must also collect, analyze, and publish data concerning organ donation and transplantation.

2. Purpose and Use of Information

Collection of data for the ZIKV pilot project will be from those OPOs that agree to participate. The data collected under this project will be analyzed to determine the potential effect of making screening tests for ZIKV available, when appropriate, to improve transplant safety, and to inform future OPTN policy regarding testing organ donors for ZIKV.

3. Use of Improved Information Technology

Since October 25, 1999, the OPTN has used an electronic data collection system to reduce the paperwork burden on the data providers (transplant programs, OPOs, and histocompatibility labs) and to minimize any intrusion into the immediate processes of organ procurement and transplantation. For example, transplant candidates can be registered and their critical data updated through direct electronic access with the central OPTN computer, which maintains the national waiting list.

The ZIKV Pilot Project allows the OPTN to gauge its responsiveness to a public health situation and to develop an IT infrastructure for future data collection or pilot projects. The data collection form will appear only for those OPOs that choose to participate in the pilot study.

4. Efforts to Identify Duplication

The OPTN data system is the only data collection effort in the United States encompassing living and deceased organ donors, transplant candidates and transplant recipients for all organ transplants (i.e., kidney, heart, heart-lung, lung, liver, pancreas, kidney-pancreas, intestines, vascularized composite allografts). This is the most comprehensive data analysis system for a single mode of therapy anywhere in the world. Prior to this donor screening test, OPOs have not had an option to screen donors for ZIKV. Therefore, this will be their first opportunity to do so and the validation system built into UNetSM will limit donor screening to one test per donor. UNetSM is the IT system used by transplant centers and organ procurement organizations to list patients on the waiting list and match patients to available organs. The OPTN also collaborated with Center for Disease Control and Prevention (CDC) to ensure efforts are consistent with previous ZIKV blood screening documentation.

5. Involvement of Small Entities

This project will not collect any data from small businesses as defined by OMB. The data collected will not have any significant impact on small business or other small entities.

6. Consequences if Information Collected Less Frequently

The primary goal is to develop a framework within the IT infrastructure to handle cases of expedited data collection. The framework will efficiently manage data entry at any level of frequency. According to the CDC's Blood & Tissue Safety: Geographic Areas with Zika Virus Transmission Risk website, there are currently no active areas at risk for the transmission of the ZIKV in the Continental United States. Therefore, data collected on a less frequent basis will not have a direct impact on assessing the transmission of ZIKV.

7. Consistency with the Guidelines in 5 CFR 1320.5

This data collection is consistent with the guidelines under 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The 60-day notice, required by 5 CFR 1320.8(d), was published in the *Federal Register* on February 9, 2018 (vol. 83 No. 28 pp. 5794-5795). No comments were received.

The contractor consulted extensively with the ZIKV Pilot Project Workgroup throughout the process of developing the elements for data collection. The workgroup consists of three OPO representatives, two transplant surgeons who specialize in infectious diseases, and two CDC representatives.

Research and data management staff employed by the current OPTN contractor, UNOS, have reviewed this form extensively and may be contacted at the following address:

United Network for Organ Sharing (UNOS)
Contact Person: Maureen McBride
700 North 4th Street

Richmond, Virginia 23219
Phone: 804/782-4649
Fax: 804/782-4835

Specific UNOS staff who provided input on the development of the form are:

Maureen McBride, PhD, Chief, Contract Operations Officer
Alexander Garza, Research Project Leader, Research Department
Justin McElroy, Associate Software Engineering Manager, IT

The design and development of the OPTN ZIKV data collection form have involved consultation not only with the providers of the data, but also with other Federal Government entities and members of the transplant community. The most significant collaborative efforts to date have been with the CDC.

9. Remuneration of Respondents

Participating OPOs will receive funding from the OPTN to help cover potential expenses, such as lab testing costs and additional staff time needed for screening patients and reporting to the OPTN. Participating OPOs receive a fixed financial payment of \$15,000 each to help offset costs associated with participating in the project. The fixed amount was calculated based on the remaining budget allocated for this contract task after staff time and other costs were considered.

The projected number of participants is 20.

10. Assurances of Confidentiality

All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected under the OPTN and SRTR contracts also are well protected by a number of the contractor's security features. HRSA certifies that UNOS's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. These security features include:

Captured Accounts

All accounts utilized by organ procurement organizations are captured accounts. This means that, once an authorized individual gains access to the contractor's computer system by an account/password combination, he/she cannot execute any commands except those for which he/she is authorized. When he/she exits the contractor's software, he/she is automatically logged off the system.

Limited Access

There is extremely limited physical access to the contractor's computer system. The UNOS premises are personally monitored 24 hours a day, 7 days a week. The building is equipped with security cameras that are monitored 24/7. No one can enter the computer area without authorization. There is an electronic pass-card-activated system in place. Card readers are at the main building entrances,

elevators, data center and all telecommunication access panels. Also, for the data center and telecommunications panels, a personal pin code must be provided in addition to the pass-card. Finally, all systems reside in locked cabinets. Two-factor authentication is required to access the keys to the cabinets.

Encrypted Identifiers

All web traffic is encrypted using SSL version 1.2 or higher.

Disaster Recovery

The contractor maintains an up-to-date Continuity of Operations Plan (COOP), which contains emergency operations, backup operations, and recovery plans to ensure continuous operation of the systems facility. System failover and recovery is tested quarterly. The contractor uses a third party co-location site for its COOP.

Paper Documents

No paper documents are maintained.

Confidentiality Agreements

All of the contractor's personnel have signed confidentiality agreements stating they will not reveal sensitive data to unauthorized individuals. The contractor has agreed to comply with the requirements of the Privacy Act as it pertains to the data in this system. A Privacy Act System of Records has been established for this project (09-15-0055). Notification of an altered system of records was published in the Federal Register on September 8, 2003 (68 FR 52950).

11. Questions of a Sensitive Nature

The Organ Procurement Organization's final rule (42 CFR Parts 413, 441, et al. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations [OPOs]; Final Rule) which was published by CMS on May 31, 2006, includes a requirement at 42 CFR § 486.344(b) (potential donor evaluation) that the OPO must "Determine whether there are conditions that may influence donor acceptance," and "If possible, obtain the potential donor's medical and social history." Presumably, obtaining such information would require an OPO to ask the potential donor's family questions of a sensitive nature, such as whether the potential donor's social history included behavior that could have resulted in ZIKV infection.

12. Estimates of Annualized Hour Burden

The following is an estimate of the annual respondent burden.

Section/ Activity	Number of Respondent s	Average Number of Responses per Responden t	Total Number of Response s	Average Burden per Response e (in hours)	Total Burde n Hours	Wage Rate	Total Hour Cost
Zika Data Collection Tool	20	58	1160*	.508	589	\$34.7 0	\$20,438. 3.
Total	20		1160*	.508	589		\$20,438. 3

*Total number of responses determined by applying the percentage of OPOs participating to the total number of deceased donors in 2016. In addition, donors screened for Zika will be based on OPO specific screening criteria. Since all donors will not be screened, this number represents 35% of the donors recovered at the 20 OPOs. Based on OPTN data as of November 9, 2017.

Basis for Burden Estimates:

The information collected through the burden assessment is based on an estimate of the average time required for selected participants to complete the new data collection form. Staff time for screening and reporting was also factored into the burden estimates.

These estimates are also based on the current number of OPOs budgeted to participate in the ZIKV Pilot Project.

The estimated number of responses is based on applying the percentage of OPOs participating to the total number of deceased donors recovered at all OPOs during 2016 (OPTN data as of November 9, 2017). Not all OPOs will participate in the pilot project. The number of responses per respondent is calculated by dividing the number of responses by the number of respondents. The estimated burden included in the 60-day notice (1,696.7 hours) has been reduced since it was determined that not all organ donors at participating OPOs will be screened for ZIKV. OPOs will be applying OPO-specific screening criteria for the ZIKV testing. As such, the total burden in the 30-day notice is estimated at 5898 hours.

Basis for Hour Costs:

OPOs collect and report data through a variety of personnel, including procurement coordinators, nurses, laboratory technicians, and medical record specialists. The individual(s) responsible for filling out the data collection forms will vary among the respondents. Therefore, for purposes of estimating the cost to the respondents, the average hourly wage reflects the mean hourly wage of a Registered Nurse by United States Department of Labor - Bureau of Labor Statistics [website](#). The mean hourly wage as of May 2016 for this position is \$34.70. The estimated cost to respondents is as follows: 589 total burden hours x \$34.70 = \$20,438.3

13. Estimates of Annualized Cost Burden to Respondents

Capital costs and start-up costs:

The OPTN system has been in place for many years; there are no capital or start-up costs for the basic network. OPTN’s UNetSM system is internet-based and, therefore, does not carry capital or start-up costs. Additionally, facilities are equipped with PCs and Internet connections and should incur no costs.

Operation and maintenance costs:

Users have computers for their normal business activities and, therefore, will not need to change maintenance practices for this purpose. Some users do have internal import/export systems that assist in the completion of these forms via their electronic medical record systems.

14. Estimates of Annualized Cost to the Government

The annual cost to the Federal Government consists of those costs allocated to the data system under the HRSA contract for the OPTN. There also is the cost to the government to monitor the data system.

Listed below are costs from the 2017 OPTN budget for OPTN Task #19 “Zika Virus Pilot Project.”

A. OPTN contract (HRSA 234-2005-37011C) – Modification No. 34

Total Direct Cost	
1. Direct Salaries and Wages	\$ 24,812
2. Fringe Benefits	11,915
3. Travel	0
4. Other Direct Costs	<u>300,600</u>
Total Direct Costs	\$337,327
Indirect Costs	<u>47,765</u>
TOTAL ESTIMATED COST	\$385,092

15. Changes in Burden

Not applicable as this is a new information collection request.

16. Time Schedule, Publication and Analysis Plans

The Zika Virus Pilot Project is a required task under the current OPTN contract, which will end on September 30, 2018. At this time there are no plans to continue the project past that date. The contractor will collect the proposed ZIKV data elements and submit a cumulative donor level dataset monthly to the COR. Each subsequent submission will include data from all prior months of the performance period up to and including the most recent month of data.

The ZIKV Pilot Project will allow the OPTN to gauge its responsiveness to emerging public health situations and to develop an IT infrastructure for future expedited data collection efforts. Outcome metrics used to determine success will include the amount of time needed to develop the data collection tool, the amount of time to release the data collection tool to the OPO members, and number and type of problems reported by the users when entering data. A process will be put in place so that OPOs can

report problems to the OPTN via the UNetSM Service Desk, which currently assists and records all issues brought to its attention. In addition, the OPTN project manager of the Zika Pilot Project record any issues reported to him.

All provisions of the Privacy Act of 1974 will be strictly enforced.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This information collection fully complies with the guidelines set forth in 5 CFR 1320.9. The certifications are included in the package.