



Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Zika Virus Pilot Project, OMB No. 0906-xxxx - NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Zika Virus Pilot Project, OMB No. 0906-xxxx – NEW

Abstract: HRSA is requesting the Organ Procurement and Transplantation Network (OPTN) perform a federally sponsored data collection as part of a pilot project to monitor the testing of deceased potential donors possibly exposed to the Zika virus (ZIKV). The Zika Pilot Project will have a 12-month performance period enabling OPTN to develop a plan to collect data on ways for organ procurement organizations (OPOs) to deploy ZIKV donor screening tests of blood products. The testing is available under an investigational new drug application for use on a voluntary basis in the evaluation of deceased persons as potential solid organ donors. OPTN will conduct an analysis of the data collected under this project to determine the potential effect of making available screening tests for ZIKV, when appropriate, to improve transplant safety. OPTN will convene a group of stakeholders to provide guidance and monitor progress on the ZIKV pilot project.

Need and Proposed Use of the Information: ZIKV is prevalent in several areas of the United States. Currently, there is not a ZIKV screening procedure for OPOs to implement during the organ allocation process. HRSA requested OPTN to conduct a pilot project to monitor the testing of deceased donors potentially exposed to ZIKV. The goals of the pilot project are to:

- Collaborate with experts to define necessary data elements to understand the impact of ZIKV testing in deceased organ donors;
- Deploy a data collection tool to a limited number of OPOs that agree to participate in the pilot project; and
- Assess the ability of OPTN to respond to a public health situation by collecting data from impacted members of the transplant community to assess the national experience.

Likely Respondents: Organ Procurement Organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Zika Data Collection Tool	20	58	1160*	.508	589
Total	20		1160*		589

*Total number of responses determined by applying the percentage of OPOs participating to the total number of deceased donors during 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.

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Acting Director, Division of the Executive Secretariat.

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