

**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
ZIKV Data Collection Tool .....	20	167	3,340	.508	1,696.7
Total .....	20	.....	3,340	.....	1,696.7

\* Total number of responses determined by applying the percentage of OPOs participating to the total number of deceased donors in 2016. Based on OPTN Data as of 11/09/2017.

\*\* Donors screened for ZIKV will be based on OPO specific screening criteria.

*HRSA specifically requests comments on:* (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Amy McNulty,**

*Acting Director, Division of the Executive Secretariat.*

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2018, 08:30 a.m. to January 22, 2018, 05:00 p.m., Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814 which was published in the **Federal Register** on December 28, 2017, 82 FR 61577. This meeting is being amended to change the date from January 22, 2018 to February 23, 2018. The time has not changed. The meeting is closed to the public.

Dated: February 5, 2018.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Eye Institute Special Emphasis Panel, January 22,

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel; Multi-site Clinical Trials.

**Date:** February 16, 2018.

**Time:** 1:00 p.m. to 4:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

**Contact Person:** Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301-827-5820, [hiromi.ono@nih.gov](mailto:hiromi.ono@nih.gov).