

Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft document entitled “Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.” The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for testing living donors for WNV. The draft guidance recommends an FDA-licensed NAT to test living donors of HCT/Ps for evidence of infection with WNV. The guidance does not provide recommendations regarding testing of cadaveric HCT/P donors for WNV. FDA believes that the use of an FDA-licensed NAT will reduce the risk of transmission of WNV from living donors of HCT/Ps and therefore recommends that you use an FDA-licensed NAT for testing living donors of HCT/Ps for infection with WNV. The 2007 Donor Eligibility Guidance indicated that FDA may recommend routine use of an appropriate, licensed donor screening test(s) to detect acute infections with WNV using NAT technology, once such tests were available.

In the **Federal Register** of October 24, 2013 (78 FR 63476), FDA announced the availability of the draft guidance entitled “Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated October 2013 (October 2013 draft guidance). FDA received several comments on the draft guidance and those comments were considered as this draft guidance was developed.

In the **Federal Register** of February 28, 2007 (72 FR 9007), FDA announced the availability of the 2007 Donor Eligibility Guidance. FDA issued a revised version of this guidance under the same title, dated August 2007 (2007 Donor Eligibility Guidance).

The draft guidance announced in this notice replaces the October 2013 draft guidance and when finalized, will supplement sections IV.E. (recommendations 15 and 16), IV.F. (recommendation 5), and supersede the “West Nile Virus (WNV)” section in

Appendix 6 of the 2007 Donor Eligibility Guidance.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-31405 Filed 12-14-15; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Indian Health Service**

[OMB Control Number 0917-0034]

#### **Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Indian Health Service published a 30 day **Federal Register** notice in the **Federal Register** (FR) on November 17, 2015 (80 FR 71813) to solicit comments from the general public on the information collection titled, “Indian Health Service (IHS) Sharing What Works—Best Practice, Promising Practice, and Local Effort (BPPPLE) Form,” Office of Management and Budget (OMB) Control Number 0917-0034. The notice was submitted before the 60 day FR notice comment period for the same information collection ends on December 8, 2015. Therefore, the correct date for the deadline to submit comments regarding the 30 day FR notice is January 9, 2016.

**ADDRESSES:** *Direct Your Comments to OMB:* Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Tamara Clay by one of the following methods:

- *Mail:* Tamara Clay, Information Collection Clearance Officer, Indian Health Service, Office of Management Services, Division of Regulatory Affairs, 5600 Fishers Lane, Rockville, Mail Stop 09E70, MD 20857.
- *Phone:* 301-443-4750.
- *Email:* [Tamara.Clay@ihs.gov](mailto:Tamara.Clay@ihs.gov).

**SUPPLEMENTARY INFORMATION:**

**Corrections**

In the **Federal Register** of November 17, in FR Doc. 2015-29251, on page 71814, in the middle column, under the heading *Comment Due Date*, the due date is corrected to read as January 9, 2016.

Dated: December 4, 2015.

**Robert G. McSwain,**

*Principal Deputy Director, Indian Health Service.*

[FR Doc. 2015-31534 Filed 12-14-15; 8:45 am]

**BILLING CODE 4165-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Clinical Trial

Implementation Cooperative Agreement (U01).

*Date:* January 22, 2016.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G41, NIAID/NIH/DHHS, 5601 Fishers Lane, Bethesda, MD 20892-7616, 240-669-5067, [pamstad@niaid.nih.gov](mailto:pamstad@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Applications (P01).

*Date:* January 22, 2016.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G41, NIAID/NIH/DHHS, 5601 Fishers Lane, Bethesda, MD 20892-7616, 240-669-5067, [pamstad@niaid.nih.gov](mailto:pamstad@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 9, 2015.

**Natasha M. Copeland,**

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

[FR Doc. 2015-31434 Filed 12-14-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 of Allergy and Infectious Diseases Special Emphasis Panel.

*Date:* January 28, 2016.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Room 4H100, 5601 Fishers Lane, Rockville, MD 20892, (Virtual Meeting).

*Contact Person:* Amir Emanuel Zeituni, Ph.D., Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC-9834, Rockville, MD 20852, 301-496-2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 9, 2015.

**Natasha M. Copeland,**

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

[FR Doc. 2015-31435 Filed 12-14-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research (CC)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Clinical Center, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*To Submit Comments and for Further Information:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic,