College of Health and Human Services

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Effectiveness of Donor Notification, HIV Counseling, and Linkage of HIV Positive Donors to Health Care in Brazil

AGENCY: National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH), Department of Health and Human Services.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 8, 2015, page 18853 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health (NIH) may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented and were referred to HIV counseling and testing centers participating in these studies completed an audio computer-assisted structured interview (ACASI) that elicited responses on demographics, risk factors/behaviors, and HIV knowledge. At the same time, a blood sample was drawn and tested for HIV genotype and drug resistance. In addition, recent infection status was determined using detuned antibody testing of samples from the original blood donation. All enrolled participants received counseling by a blood bank physician and were referred to HIV counseling and testing centers (HCT).

New information gathered from these enrollees will serve the three aims proposed for this proposed study. The first aim of this study will be to analyze the actual percentage of blood donors who are successfully notified of their infection testing results. In this aim, we will expand the notification focus to include all infections that blood centers in Brazil test for because differences in rates of notification by type of infection are unknown. The second aim will assess the effectiveness of HIV notification and counseling. HIV-positive donors will be interviewed to evaluate their follow-up activities with regard to HIV infection treatment and infection transmission prevention behavior after notification by the blood center. This will be accomplished using a new audio computer-assisted structured interview (ACASI) (See Attachment 1, Brazil HIV Follow up ACASI Survey). The third aim will consist of asking HIV-positive blood donors about ways to improve the disclosure of HIV risks during donor eligibility assessment to better understand the motivating factors that

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FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301-435-0606, or Email your request, including your address to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Proposed Collection: The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil, 0925–0597, expired on February 29, 2012) and those enrolled during the REDS–III HIV case surveillance risk factor study (OMB 0925–0597, expiration date, July 31, 2015), between 2012 and 2014. Donor enrollees at any of the four blood centers participating in these studies completed an audio computer-assisted structured interview (ACASI) that elicited responses on demographics, risk factors/behaviors, and HIV knowledge. At the same time, a blood sample was drawn and tested for HIV genotype and drug resistance. In addition, recent infection status was determined using detuned antibody testing of samples from the original blood donation. All enrolled participants received counseling by a blood bank physician and were referred to HIV counseling and testing centers (HCT).

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Estimates of the annual burden of respondents are estimated as follows:

<table>
<thead>
<tr>
<th>Activity name</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examining consent forms for participation in PATH Study</td>
<td>Adults</td>
<td>200</td>
<td>1</td>
<td>90/60</td>
<td>300</td>
</tr>
<tr>
<td>Examining consent forms for participation in PATH Study</td>
<td>Youth</td>
<td>200</td>
<td>1</td>
<td>90/60</td>
<td>300</td>
</tr>
<tr>
<td>Examining consent forms for participation in PATH Study</td>
<td>Adults</td>
<td>200</td>
<td>1</td>
<td>90/60</td>
<td>300</td>
</tr>
<tr>
<td>Examining consent forms for participation in PATH Study</td>
<td>Youth</td>
<td>100</td>
<td>1</td>
<td>90/60</td>
<td>150</td>
</tr>
<tr>
<td>Examining consent forms for participation in PATH Study</td>
<td>Adults</td>
<td>300</td>
<td>1</td>
<td>90/60</td>
<td>450</td>
</tr>
</tbody>
</table>

Dated: June 23, 2015.

Genevieve deAlmeida-Morris, Project Clearance Liaison, NIDA, NIH.

[FR Doc. 2015–15844 Filed 6–29–15; 8:45 am]

BILLING CODE 4140–01–P
drive higher risk persons to donate blood.

Because our study will build off the routine blood donor procedures in four large blood banks in Brazil, it may lead to more informed conversations around and possible changes in donor screening, notification and counseling policies in Latin America. Results of these three aims may also help to better integrate blood centers within the context of broader HIV testing, counseling and treatment sites in Brazil. Similarly, in the US little is known about donor behavior after notification of testing results by blood centers. The results from this study can be used to develop insights and hypotheses focused on developing improved strategies for notification and counseling of HIV-positive (or hepatitis C or B-positive) donors in the U.S.

This proposed study’s findings will also yield insights into improved methods for donor self-selection and qualification post donation, which will serve to decrease the frequency of higher-risk persons acting as donors. Our findings on improved methods for Brazilian donor notification and linkage to health care services may also be applicable to developed countries, including the U.S. Results of the Brazil Notification Study will identify how to improve notification and counseling strategies that increase the number of HIV-positive donors seeking prompt medical care. This might ultimately boost strategies to prevent secondary HIV transmission and reduce the risk of transfusion-transmission.

In addition to the traditional route of scientific dissemination through peer reviewed scientific publication, previous REDS and REDS–II study data were the subject of numerous requested presentations by Federal and non-Federal agencies, including the FDA Blood Products Advisory Committee, the HHS Advisory committee on Blood Safety and Availability, the AABB Transfusion-Transmitted Diseases Committee, and the Americas Blood Centers (ABC). We anticipate similar requests for results generated from this study. Data collected in this proposed HIV Notification study of donors will be of practical use to the blood banking and infectious disease communities in the US and internationally.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 229.

### ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Form name</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response</th>
<th>Estimated total annual burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACASI Questionnaire—Informed Consent</td>
<td>Adults ..................</td>
<td>275</td>
<td>1</td>
<td>10/60</td>
<td>46</td>
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<tr>
<td>ACASI Questionnaire</td>
<td>Adults ..................</td>
<td>275</td>
<td>1</td>
<td>40/60</td>
<td>183</td>
</tr>
</tbody>
</table>

Dated: June 16, 2015.

Valery Gheen, NHLBI Project Clearance Liaison, National Institutes of Health.

NHLBI Project Clearance Liaison, National Institutes of Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

Date: July 6, 2015.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lawrence E. Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435–8367, boerboom@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Asthma, Pulmonary Fibrosis and Inflammation.

Date: July 6–7, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, nussb@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Date: July 6, 2015.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Clary, Program Analyst, Office of Federal Advisory Committee Policy.

Date: June 24, 2015.

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