Requirements Concerning Gowns Intended for Use in Health Care Settings'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500025 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subparts A through D have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

## V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: June 25, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–16011 Filed 6–29–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 60-Day Comment Request; Population Assessment of Tobacco and Health Study

**AGENCY:** National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), Department of Health and Human Services.

**SUMMARY:** In compliance with the requirements of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), 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.

**DATES:** *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** *To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address to: *PATHprojectofficer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Proposed Collection:* Cognitive Interviews and Focus Groups for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925–0663–Revision, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

*Need and Use of Information Collection:* This is a revision request (OMB 0925–0663, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct cognitive interviews and focus groups, to support the development of the Study's questionnaires and other materials. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual interviews and collects biospecimens from adults to inform FDA's regulatory actions under the Family Smoking Prevention and Control Act. Cognitive interviews and focus groups are qualitative methods to assess how people interpret, process, retrieve, and respond to phrases, questions, response options, and product images that may be used in the development of the PATH Study's questionnaires and other materials. These methods have previously been used to help the PATH Study improve the comprehensibility of its materials for Study participants, and to increase efficiencies in data collection and reduce duplication and its associated burden on participants and the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 2,400.

ESTIMATED ANNUALIZED BURDEN HOURS

| Activity name | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|---|---|---|---|---|---|
| Completing eligibility screener | Youth | 1,200 | 1 | 10/60 | 200 |
| | Adults | 2,400 | 1 | 10/60 | 400 |
| Examining concepts to be measured in PATH Study. | Adults | 200 | 1 | 90/60 | 300 |

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Activity name | Type of respondent | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|---|---|---|---|---|---|
| Examining assent forms for participation in PATH Study. | Youth | 200 | 1 | 90/60 | 300 |
| Examining consent forms for participation in PATH Study. | Adults | 200 | 1 | 90/60 | 300 |
| Examining other forms and materials to support PATH Study data collection. | Adults | 200 | 1 | 90/60 | 300 |
| Examining PATH Study questionnaires | Youth | 100 | 1 | 90/60 | 150 |
| | Adults | 300 | 1 | 90/60 | 450 |

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**

## DEPARTMENT 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 on or after October 1, 1995, unless it displays a currently valid OMB control number.

**DATES:** *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** *Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

**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 301-435–0065, 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-New, National Heart, Lung and Blood Institute (NHLBI).

*Need and Use of Information Collection:* The prevention of transfusion-associated transmission of HIV is one of the greatest success stories in the fight against the HIV epidemic; however, the job is unfinished. In some middle-and low-income countries, blood transfusion may account for up to 6% of HIV infections (1). Currently, all blood donors who test positive or inconclusive for HIV or other sexually transmitted diseases are notified (donor notification) and requested to follow-up with the blood bank for potential confirmatory testing and referral to specific health services, such as monitoring and treatment. Little is known about the consequences of blood donor notification and subsequent monitoring and counseling on efforts to control the HIV epidemic in the United States and internationally. The Brazil Notification Study team proposed to addresses this significant information gap by enrolling all former blood donors who participated in the REDS–II HIV case-control study (OMB 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).

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