



[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 E-mail 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 address 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 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 US. 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

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response	Estimated Total Annual Burden Hours Requested
ACASI Questionnaire - Informed Consent	Adults	275	1	10/60	46
ACASI Questionnaire	Adults	275	1	40/60	183

Dated: June 16, 2015.

Valery Gheen
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