

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; HIV Study in Blood Donors From Five Chinese Regions

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 National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

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.

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: 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.

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.

Proposed Collection: HIV Study in Blood Donors from Five Chinese Regions, 0925-0596 reinstatement with change, National Heart, Lung and Blood Institute (NHLBI).

Need and Use of Information Collection: This Study is a reinstatement of OMB Number: 0925-0596 expiration date, January 31, 2012. To better understand the diversifying and changing Human Immunodeficiency Virus (HIV) epidemic, and contemporary HIV risk factors, especially those associated with recent HIV infections, this HIV risk factor study in China is proposed as part of the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III). The major objectives of the study will be to evaluate the proportion of blood donors in China who test positive for HIV and have acquired their infection recently or more remotely; the risk of releasing a blood product that contains HIV (HIV residual risk); and the risk factors associated with HIV infection in China. The study will also assess the frequency of distinct HIV-1 viral lineages and drug resistant mutations among HIV-positive blood donors. In 2011, there were 780,000 people infected with HIV in China and it is estimated that over 300,000 HIV infected people in China are not aware of their infection status. The large migrating population and the complexity of HIV transmission routes in China make it difficult to implement a comprehensive and effective national HIV control strategy. Risk factors for infections can change over time; thus, identifying factors that contribute to the recent spread of HIV in a broad cross-section of an otherwise unselected general population, such as blood donors, is highly important for obtaining a complete picture of the epidemiology of HIV infection in China. Because the pace of globalization means infections can cross borders easily, the study objectives have direct relevance for HIV control in the U.S. and globally. Recent years have seen an increase in blood donations from repeat donors in most Chinese regions. This increase permits longer-term follow-up and testing of repeat donors which allow for calculation of new HIV infection rates and residual risks. The HIV data, for both recently and remotely acquired infections, from the proposed study will complement existing data on HIV risks obtained from general and high risk populations to provide comprehensive HIV surveillance data for China. This study will also monitor genetic characteristics of recently acquired infections through genotyping and drug resistance testing, thus serving a U.S.

and global public health imperative to monitor the genotypes of HIV that have recently been transmitted. For HIV, the additional monitoring of drug resistance patterns in newly acquired infection is critical to determine if currently available antiretroviral medicines are capable of combating infection. Genotyping and host response information are scientifically important not only to China, but to the U.S. and other nations since they provide a broader global understanding of how to most effectively manage and potentially prevent HIV, for example through vaccine development. Efforts to develop vaccines funded by the National Institutes of Health and other U.S.-based organizations may directly benefit from the findings of this study.

Blood donors are tested for transfusion-transmissible infections including HIV when they present to donate, and test result information as well as demographic data will be routinely collected in a database at the five blood centers participating in REDS-III studies (located in the cities of Chongqing, Liuzhou, Luoyang, Mianyang, and Urumqi). These data will allow for calculation of HIV incidence, prevalence, and residual risk. Additionally, a case-control study will be conducted over a 2 and 1/2 year period to evaluate the risk factors associated with HIV infection among blood donors. Cases will be defined as potential donors who deny risks on the donor screening questionnaire but are found to be positive on HIV testing (their donation is discarded). HIV-positive donors who gave blood at one of the five blood centers as stated above (primary sites) or at blood centers located in the Guangxi Autonomous Region (peripheral sites, recruited through the Guangxi CDC for this study only but not other REDS-III studies) will be eligible to participate and complete a Risk Factor Questionnaire that will assess general demographic and risk factor information pertinent to HIV infection. Controls will be negative for HIV on confirmatory testing. Assuming 50% response rate, it is anticipated that 390 HIV-positive donors and 960 controls will participate in the case control study. The results of this study will contribute to global HIV surveillance and prevention, provide a broader global understanding of HIV epidemiology, and support public health efforts to most effectively manage and potentially prevent HIV transmission both worldwide and in the U.S.

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

estimated annualized burden hours are 450.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
HIV Risk factor Q	Blood donors—Case Primary Sites	210	1	20/60	70
	Blood donors—Case peripheral sites	180	1	20/60	60
	Blood donors—Control primary sites	540	1	20/60	180
	Blood donors—Control—peripheral sites	420	1	20/60	140
	Blood donors—total	1,350	1	20/60	450

Dated: May 29, 2014.
Keith Hoots,
 Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH.

Dated: May 29, 2014.
Lynn Susulske,
 NHLBI Project Clearance Liaison, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The National Diabetes Education Program (NDEP) Comprehensive Evaluation Plan

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 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 March 19 2014, pages 15351 and 15351[FR DOC #: 2014-06064], and allowed 60 days for public comment. There was 1 public comment received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health 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.

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.

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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Ms. Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, OCPL, NIDDK, 31 Center Drive, MSC 2560, Bethesda, MD 20892, or call non-toll-free number 301-496-6110, or Email your request, including your address to: *joanne_gallivan@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The National Diabetes Education Program (NDEP) Comprehensive Evaluation Plan, 0925-0552, Expiration Date 10/31/2015, REVISION, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goal of the NDEP is to reduce the burden of diabetes and pre-diabetes in the United States, and its territories, by facilitating the adoption of proven strategies to prevent or delay the onset of diabetes and its complications.

The NDEP evaluation will document the extent to which the NDEP program has been implemented and how successful it has been in meeting program objectives, outlined in the NDEP Strategic Plan. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This is a continued collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. The audiences targeted by the NDEP include people at risk for diabetes, people with diabetes and their families, and the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 841.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent and instrument	Estimated number of respondents	Estimated number of responses per respondent	Average time per response (in hours)	Estimated total annual burden hours
Adults—Pretest surveys	25	1	20/60	8
Adults—Surveys	2500	1	20/60	833