CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Molecular Diagnostic Instruments With Combined Functions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1763 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, 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; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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: November 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26694 Filed 11–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; HIV Study in Blood Donors From Five Chinese Regions (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) 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** in Volume 79, June 12, 2014 on page 33764 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Chinese blood donation system. 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.

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.

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: 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.

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 with change 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 US 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 US 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 US 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 US-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 US.

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

Dated: October 28, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–26761 Filed 11–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Institute of Mental Health (NIMH) Draft Strategic Plan; Request for Comments

SUMMARY: NIMH is revising its 2008 Strategic Plan to guide the Institute's research efforts and priorities over the next five years (2015–2020). The purpose of this Notice is to seek input from the public about the draft NIMH 2015 Strategic Plan. The draft plan will be publicly available through the NIMH Draft Strategic Plan Web page (*http://www.nimh.nih.gov/about/strategic-planning-reports/review-the-draft-2015-nimh-strategic-plan.shtml*) for a 30-day period beginning on the publication date of this Notice. The public is invited to provide comments via the email address or postal address provided in this Notice and on the NIMH Draft Strategic Plan Web page.

DATES: To ensure consideration, your responses must be received within a 30-day period that begins on the publication date of this Notice.

ADDRESSES: Responses to this Notice should be submitted electronically using email to *nimhstratplan@mail.nih.gov.* Alternatively, written responses can be submitted by mail to the Science Writing, Press, and Dissemination Branch, 6001 Executive Boulevard, Room 6200, MSC 9663. Bethesda, MD 20892–9663.

FOR FURTHER INFORMATION CONTACT: Please contact our NIMH Information Specialists using the following contact information: telephone: 1–866–615–6464 (toll-free), 1–301–443–8431 (TTY), 1–866–415–8051 (TTY toll-free). Fax: 1–301–443–4279, Email: *nimhinfo@nih.gov*

SUPPLEMENTARY INFORMATION:

Background

The National Institute of Mental Health (NIMH) is the lead federal agency for research on mental illnesses. The mission of the NIMH is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. To fulfill its mission, the NIMH supports and conducts research on mental illnesses and the underlying basic science of brain and behavior; supports the training of scientists to carry out basic and clinical mental health research; and, communicates with scientists, patients, providers, and the general public about the science of mental illnesses.

In 2008, the NIMH published a Strategic Plan to accelerate progress in basic, translational, and clinical science. The need to update the plan became clear with the increasing number of remarkable scientific advancements and the changing landscape of mental health care over the past six years. With the goals of helping individuals living with mental illnesses and promoting both prevention and cure, NIMH has revised its original four high-level Strategic Objectives as follows: (1) Define the biological basis of complex behaviors; (2) chart mental illness trajectories to determine when, where, and how to intervene; (3) develop better preventive and therapeutic interventions; and, (4) strengthen the public health impact of NIMH-supported research. These four Strategic Objectives form a broad roadmap for the Institute's priorities over the next five years, which begins with the fundamental science of the brain and behavior, and ends with public health impact. Full implementation of these Strategies Objectives, will, we hope, transform the