[NIH Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; comment request

Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

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.

PROPOSED COLLECTION: *Title:* Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil. *Type of Information Collection Request: Extension* (OMB No. 0925-0597). *Need and Use of Information Collection:* Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral treatment, and enabling documentation of the rates of primary transmission of anti-viral drug resistant strains in the community. This study is a continuation of a previous research project which enrolled eligible HIV positive blood donors and analyzed HIV molecular variants and their association with risk.

This previous project was conducted by the NHLBI Retrovirus Epidemiology Donor Study –II (REDS-II) International Brazil program and included not only data collection on HIV seropositive donors but also collection of risk factor data on uninfected donors. The current Recipient Epidemiology and Donor Evaluation Study -III (REDS-III) research proposal is a continuation of the previous REDS-II project at the same four blood centers in Brazil, located in the cities of Sao Paulo, Recife, Rio de Janeiro and Belo Horizonte, but this time restricted to the study of HIV-positive subjects.

The primary study aims are to continue monitoring HIV molecular variants and risk behaviors in blood donors in Brazil, and to evaluate HIV subtype and drug resistance profiles among HIV positive donors according to HIV infection status (recent versus long-standing infection), year of donation, and site of collection. Additional study objectives include determining trends in HIV molecular variants and risk factors associated with HIV infection by combining data collected in the previous REDS-II project with that which will be obtained in the planned research activities.

Nucleic acid testing (NAT) testing for HIV is currently being implemented in Brazil. It will be important to continue to collect molecular surveillance and risk factor data on HIV infections, especially now that infections that might not have been identified by serology testing alone could be recognized through the use of NAT. NAT-only infections represent very recently acquired infections. The NAT assay will be used at the four REDS-III blood centers in Brazil during the planned research activities. In addition, in order to distinguish between recent seroconversion and long-standing infection, samples from all HIV antibody- dual reactive donations and/or NAT positive donations will be tested by the Recent Infection Testing Algorithm (*RITA*) which is based on use of a sensitive/less-sensitive enzyme immunoassay ("detuned" Enzyme Immunoassay). RITA testing will be performed by the Blood Systems Research Institute, San Francisco, California, USA, which is the REDS-III Central Laboratory.

Subjects will be enrolled for a 5-year period from March 2012 through February 2017. According to the Brazilian guidelines, blood donors are requested to return to the blood bank for HIV confirmatory testing and HIV counseling. Donors will be invited to participate in the study through administration of informed consent when they return for HIV counseling. Once informed consent has been administered and enrollment has occurred, participants will be asked to complete a confidential self-administered risk factor questionnaire by computer. In addition, a small blood sample will be collected from each HIV positive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing will be communicated back to the HIV positive participants during an in-person counseling session at the blood center. For those individuals who do not return for confirmatory testing, the samples will be anonymized and sent to the REDS-III central laboratory to perform the recent infection testing algorithm (RITA).

This research effort will allow for an evaluation of trends in the trafficking of non-B subtypes and rates of transmission of drug resistant viral strains in low risk blood donors. These data could also be compared with data from similar studies in higher risk populations. Monitoring drug resistance strains is extremely important in a country that provides free anti-retroviral therapy for HIV infected individuals, many of whom have low level education and modest resources, thus making compliance with drug regimens and hence the risk of drug resistant HIV a serious problem.

The findings from this project will add to those obtained in the REDS-II study, allowing for extended trend analyses over a 10-year period and will complement similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the USA and other funded international REDS-III sites in South Africa and China, thus allowing direct comparisons of these parameters on a global level.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 100; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.40 (including administration of the informed consent form and questionnaire completion instructions); and *Estimated Total Annual Burden Hours Requested:* 40. The annualized cost to respondents is estimated at: $260 (based on $6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated Annual Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
100	1	0.40	40

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, 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 to: glynnsa@nhlbi.nih.gov.

COMMENTS 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.

Dated: __January 3, 2012__

_____

Keith Hoots, MD

Director, Division of Blood Diseases and Resources

National Heart, Lung, and Blood Institute, NIH

Dated: _January 3, 2012_

_____

Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

[FR Doc. 2012-571 Filed 01/12/2012 at 8:45 am; Publication Date: 01/13/2012]