[NIH Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 day comment request

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

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 non-toll-free number (301)- 435-0065, or E-mail your request to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

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.

PROPOSED COLLECTION**:** Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil 0925-0597 expiration date, July 31, 2015, Extension, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

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 are being enrolled for a 5-year period from July 2012 through 2017.. According to the Brazilian guidelines, blood donors are requested to return to the blood bank for HIV confirmatory testing and HIV counseling. Donors are 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 are asked to complete a confidential self-administered risk factor questionnaire by computer. In addition, a small blood sample is collected from each HIV positive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing are 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 40.

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
Risk Factor Assessment	Adult Donors	100	1	24/60	40

Dated: December 18, 2014.

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