4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 day comment request

Characterization of Risk of HIV and HIV Outcomes in the Brazilian Sickle Cell Disease (SCD) Population and Comparison of SCD Outcomes Between HIV Sero-Positive and Negative SCD Patients (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**:** Characterization of risk of HIV and HIV outcomes in the Brazilian Sickle Cell Disease (SCD) population and comparison of SCD outcomes between HIV sero-positive and negative SCD patients 0925-NEW, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The National Heart, Lung, and Blood Institute (NHLBI) Recipient Epidemiology and Donor Evaluation Study-III

(REDS-III) program conducts research focused on the safety of the blood supply, the patients who are in need of transfusions, and the epidemiology of transfusion-transmissible infections such as human immunodeficiency virus (HIV). Sickle cell disease (SCD) is a blood disorder that affects thousands of people in the United States and Brazil. Many patients with SCD need to be chronically transfused with red blood cells and the REDS-III research program has established in Brazil a cohort of patients with SCD to study transfusion outcomes and infectious diseases such as HIV in the SCD population.

Sickle cell disease predominantly affects persons with sub-Saharan Africa and other malaria-endemic regions ancestry because people who carry one sickle cell disease gene (you need 2 to have sickle cell disease) have a survival advantage for malaria. Sub-Saharan Africa, where most people with SCD in the world live, remains one of the regions most severely affected by HIV, with nearly 1 in every 20 adults living with the virus. In the United States, HIV also disproportionately affects persons with African ancestry. Despite the diseases' occurrence in similar populations and the fact that both HIV and SCD are independent predictors of outcomes such as stroke, there is a lack of data to evaluate if patients with SCD and HIV have different illnesses than patients who have SCD- or HIV-only. The proposed study will seek to understand the risk of HIV in the SCD population, describe HIV outcomes in patients with SCD and compare SCD complications between HIV-positive and HIV-negative patients with SCD using the infrastructure established by the REDS-III SCD Cohort study.

The limited studies focused on HIV in SCD have suggested that HIV may not occur as frequently in patients with SCD as in people who do not have SCD. While it has

been hypothesized that perhaps SCD pathophysiology has a unique effect on HIV infection or replication, none of the studies have adequately measured risk factors for HIV in patients with SCD. The first objective of the proposed study is to compare HIV risk factors between 150 patients with SCD (cases) randomly selected from the REDS-III SCD Cohort study and 150 individuals without SCD (controls) from a demographically similar population. An assessment that has been well validated in previous studies has been modified for the SCD population and will be used to collect data regarding HIV risk behaviors. The second objective of the proposed study will seek to enroll approximately 25 patients with SCD and HIV who consent to have detailed information regarding their diseases retrieved from their medical records. This will allow for an in-depth evaluation of how patients with both diseases fare. Additionally, patients who have SCD but not HIV will be compared to patients who have both diseases to better understand how one disease affects the other disease. Information on the HIV-negative patients with SCD has already been collected because they participated in the REDS-III SCD Cohort study. This study will provide critical information to guide the management and future research for patients with HIV and SCD in Brazil, the United States, and worldwide.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 325.

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours

Objective 1 Risk Factor Informed Consents	Adult SCD cases and controls	300	1	15/60	75
Objective 2 Risk Factor Informed Consent	Adult previously enrolled REDS-II and III HIV SCD patients	25	1	15/60	6
Objectives 1 and 2 Risk Factor Assessment	Adult SCD cases and controls, and Adult previously enrolled REDS-II and III HIV SCD patients	325	1	45/60	244

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