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 Email your request to: *glynnsa@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

DATES:

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

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
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

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–14–022: Improving Diabetes Management in Young Children with Type 1 Diabetes (DP3).

Date: June 24, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies: Kramer.

Date: July 10, 2015.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: July 16, 2015.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Psychosocial and Behavioral Aspects of Bariatric Surgery (R01).

Date: July 23, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Identification of Novel Targets and Pathways Mediating Weight Loss, Diabetes Resolution and Related Metabolic Disease after Bariatric Surgery in Humans (R01).

Date: July 27, 2015.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 2, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Subcommittee.

Date: June 30, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3F30A, 5601 Fisher Lane, Rockville, MD 20892.

Contact Person: Ellen S. Buczko, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Bethesda, MD 20892–7616, 240–669–5028, *ebuczko1@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,