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Dated: November 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26854 Filed 11–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: Incident HIV/Hepatitis B Virus Infections in South African Blood Donors: Behavioral Risk Factors, Genotypes and Biological Characterization of Early Infection

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 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.

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: Incident HIV/ Hepatitis B virus (HBV) infections in South African blood donors: Behavioral risk factors, genotypes and biological

characterization of early infection, 0925-New, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: South Africa has one of the highest burdens for HIV infection in the world. The HIV epidemic in South Africa is largely heterosexual, but risk factors for infections can change and so identifying factors that contribute to the recent spread of HIV in a broad cross-section of the otherwise unselected general population, such as blood donors, is highly important for obtaining a complete picture of the epidemiology of HIV infection in Africa. Small previous studies suggest that the risk factors for HIV among more recently acquired (incident) infections in blood donors may differ from those of more distant (prevalent) infections. Similarly risk factors for recently acquired HBV may be different than for prevalent HBV infections. The demographic and behavioral risks associated with incident HIV and incident HBV infection have, as yet, not been formally assessed in South African blood donors using analytical study designs. Due to the high rates of HIV and HBV infection in South African blood donors, a better understanding of these risk factors can be used to modify donor screening questionnaires so as to more accurately exclude high-risk blood donors and contribute to transfusion safety. Risk factor data from this research may also provide critical information for blood banking screening strategies in other countries.

This study which provides a contemporary understanding of the current risk profiles for HIV and separately for HBV will also prospectively monitor genetic characteristics of recently acquired infections through genotyping and drug resistance profile testing, thus serving a US, South African, and global public health imperative to monitor the genotypes of HIV and HBV 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. Because the pace of globalization means these infections can cross borders easily, these study objectives have direct relevance for HIV and HBV control in the U.S. and globally. Further, the ability to identify recent HIV infections provides a unique opportunity to study the biology, host response and evolution of HIV disease at time points proximate to virus acquisition. Genotyping and host response information is scientifically important not only to South Africa, but to the U.S. and other nations since it will provide a broader global understanding of how to most effectively manage and potentially prevent HIV (e.g. 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.

The South African National Blood Service (SANBS) uses both individual donation Nucleic Acid Testing (ID–NAT) and serology tests (either antibody or antigen detection tests) to screen blood donors for HIV and Hepatitis-B Virus (HBV), among other infections. A positive NAT test precedes HIV antibody detection or HBV surface antigen detection by days to weeks in newly acquired HIV and HBV infections. A combined testing strategy using NAT and serology tests therefore confers the ability to detect most acute infections and discriminate between recent (incident) and more remotely acquired (prevalent) infection. Additional tests that exploit antibody maturation kinetics such as the HIV Limiting Antigen Avidity assay (LAg Avidity) can further assist to classify persons with an HIV antibody positive test as having a recently acquired (incident) or longer-term (prevalent) infection. Hepatitis B core antibody (anti-HBc) testing of NAT-positive and NAT and Hepatitis B Virus Surface Antigen (HBsAg) positive HBV infections allows classification of HBV infections as recently acquired or prevalent infections. Infections that are anti-HBc negative are recently acquired (incident).

Leveraging this ability to classify HIV and HBV infections as incident or prevalent leads to three study objectives:

1. Objective 1 consists of evaluating the risk factors associated with having an incident HIV or HBV infection. To that end, a frequency matched case-control study will be conducted with two case groups: incident HIV infected blood donors and incident HBV infected blood donors, respectively. Risk factors in these two case groups will be compared to the risk factors provided by a group of controls (blood donors whose infectious tests are all negative). Cases and controls will be accrued from a geographically diverse donor pool.

2. Objective 2 consists of characterizing HIV clade and drug resistance profiles and determining viral loads in all cases of incident HIV infection, as well as characterizing HBV genotype and viral load in all incident HBV infections.

3. Objective 3 consists of following persons with incident and ''elite controller'' HIV infections prospectively for three additional visits at 2, 3, and 6 months following the index positive test(s). The term ''elite controllers'' refers to those who are HIV antibody positive, but with undetectable viral RNA (NAT negative) who are believed to have a natural ability to control viral replication without therapy. These studies will be useful in identifying appropriate HIV drug therapy regimens for this condition, as well as strategies for producing an effective HIV vaccine, which has eluded 30 years of HIV research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden for Objectives 1 and 2 will be 395 hours for 483 subjects. The total estimated annualized burden for Objective 3 will be 32 hours for 35 respondents.

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Objectives 1 and 2 consent form	Adult Donors	483	1	15/60	121
Objectives 1 and 2—ACASI Questionnaire	Adult Donors	483	1	34/60	274
Objective 3 consent form*—Year 1	Adult Donors	35	1	15/60	9
Objective 3—Clinical Follow-up Questionnaire—Year 1*.	Adult Donors	35	4	10/60	23
Objective 3 consent form*—Year 2	Adult Donors	35	1	15/60	9
Objective 3—Clinical Follow-up Questionnaire—Year 2*.	Adult Donors	35	4	10/60	23

*The Objective 3 respondents are a subset of the respondents included in Objectives 1 and 2.

Dated: October 23, 2013.

Keith Hoots,

Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, NIH.

Dated: October 24, 2013.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013–26807 Filed 11–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Molecular Genetics B (MGB).

Date: November 25, 2013.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: International Research Ethics Education and Curriculum Development.

Date: December 9, 2013.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, MSC 7770, Bethesda, MD 20892, (301) 254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Macromolecular Structure and Function D.

Date: December 9, 2013.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: James W. Mack, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–2037, *mackj2@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26754 Filed 11–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel; Member Conflict.

Date: December 18, 2013.

Time: 2:00 p.m. to 3:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Scientific Review Branch, National Institute On Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2c–212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26750 Filed 11–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biomedical Imaging Technology A Study Section, October 07, 2013, 08:00 a.m. to October 08, 2013, 05:00 p.m., Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA, 22311 which was published in the **Federal Register** on September 10, 2013, 78 FR 175 Pgs. 55268–55270.

The meeting will be held at the Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852. The meeting will start on December 10, 2013 at 6:00 p.m. and end December 11, 2013 at 5:00 p.m. The meeting is closed to the public.

Dated: November 1, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26753 Filed 11–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Review of Neuroscience AREA Grant Applications, October 24, 2013, 08:00 a.m. to October 25, 2013, 12:00 p.m., St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036, which was published in the **Federal Register** on October 01, 2013, 78 FR 60298.

The meeting will be held on December 9, 2013 to December 10, 2013. The meeting location and time remain the same. The meeting is closed to the public.