

Moderator: Ashley Golden
Moderator E-mail: a_golden@team-psa.com.

For Further Information Contact: Anyone requesting information regarding the Committee should contact Louis D. Coccodrilli, Designated Federal Official for the ACICBL, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Rm. 9-36, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443-6950 or lcoccodrilli@hrsa.gov. Marie Ulysse, HRSA Scholar, can also be contacted for inquiries at (301) 443-6529 or mulyssse@hrsa.gov.

Dated: August 4, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8-18393 Filed 8-8-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Prevalence and Incidence of HIV Molecular Variants and Their Correlation With Risk Behaviors and HIV Treatment in Brazilian Blood Donors

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 29, 2008, pages 30951-30952 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection: Title: The Prevalence and Incidence of HIV Molecular Variants and Their Correlation With Risk Behaviors and HIV Treatment in Brazilian Blood Donors. **Type of Information Collection Request:** New. **Need and Use of**

Information Collection: Establishing and monitoring viral prevalence and incidence rates, and identifying risk behaviors for HIV incidence among blood donors, are critical to assessing and reducing risk of HIV transmission through blood transfusion. Identifying donation samples from donors with recent HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population and hence most likely to "break-through" routine screening measures (i.e., peri-seroconversion window period donations). Molecular surveillance of incident HIV infections in blood donors not only characterizes genotypes of recently infected donors for purposes of blood safety, but also enables documentation of the rates of primary transmission of anti-viral drug resistant strains in the community, serving a public health role in identifying new HIV infections for anti-retroviral treatment. Both a prospective surveillance and a case-control design are proposed to enroll all eligible HIV seropositives detected at three blood centers in Brazil (São Paulo, Belo Horizonte, and Recife) plus a satellite center in Rio de Janeiro. A comparison of epidemiological risk profiles will be made between the seropositive donors and a group of randomly selected seronegative donors.

There are three study aims. Laboratory studies (LS-EIA testing and sequencing of pol region) on linked specimens from all enrolled HIV cases, will allow for estimation of HIV prevalence and incidence relative to genotype and putative route of infection. Data derived from molecular genotyping, including drug resistant genotypes, will be provided, along with counseling, to all enrolled HIV positive donors to facilitate their clinical care via referral to the Brazilian national HIV treatment system. Our findings will be compared to trends in prevalence, incidence and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broad monitoring of the HIV epidemic in Brazil and assessment of the impact of donor selection criteria on these parameters. Finally, HIV cases and a group of controls, through responses to a questionnaire, will provide data on HIV risk behaviors among prospective blood donors. This HIV risk behavior data will be used as

covariates in the molecular surveillance analyses described above, as well as aid in assessing whether modifications may be needed to Brazil's routine blood center operational donor screening questionnaire.

The study participants will return to their local blood center for the administration of an informed consent form, explaining the confidential nature of the research study as well as the risks and benefits to their participation. Once enrolled, they will be asked to complete the self-administered risk factor questionnaire. In addition, a small blood sample will be collected from each HIV seropositive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing will be communicated back to the seropositive participants during an in-person counseling session at the blood center.

Defining prevalence and incidence in blood donors and residual risk of HIV transmission by transfusions may lead to new regulations and blood safety initiatives in Brazil. The data can be used to project the yield, safety impact and cost effectiveness of implementing enhanced testing strategies such as combination antigen-antibody assays and/or NAT. Determination of HIV risk factors in donors (first time versus repeat donor status; volunteer versus replacement status; demographics and risk behaviors) will support policy discussions over strategies to recruit the safest possible donors in Brazil. The findings from this project will also complement similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the U.S. and other funded international REDS-II sites, 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:** 2,000; **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:** 800. The annualized cost to respondents is estimated at: \$5,200 (based on \$6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
2,000	1	0.40	800

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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 9144, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892-7950, or call 301-435-0065, or E-mail your request to nemog@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 1, 2008.

George Nemo,

Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8-18491 Filed 8-8-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health (NIH).

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 property.

Name of Committee: Advisory Committee to the Director, NIH.

Date: August 15, 2008.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Penny Burgoon, Senior Assistant to the Deputy Director, Office of the Director, National Institutes of Health, 1 Center Drive, Building 1, Room 114, Bethesda, MD 20892, (301) 451-5870, burgoonp@od.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.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.nih.gov/about/director/acd.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research

Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 5, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-18494 Filed 8-8-08; 8:45 am]

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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. Appendix 2), 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, Oncology Area.

Date: September 8, 2008.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lambratu Rahman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-451-3493, rahmanl@csr.nih.gov.

Name of Committee: Oncological Sciences Integrated Review Group, Cancer Molecular Pathobiology Study Section.

Date: September 15-16, 2008.

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

Agenda: To review and evaluate grant applications.