Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 25, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 17, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 18, 2012.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Martha Monser at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 5, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–8701 Filed 4–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Medical Countermeasures Initiative Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Date and Time: This symposium will be held on Tuesday, June 5 and Wednesday, June 6, 2012, from 8 a.m. to 5:30 p.m. Persons interested in attending the symposium in person or viewing via Web cast must register by Tuesday, May 29, 2012, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993–0002.

Contact: Rakesh Raghuwanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4283, 301–796–4769, FAX: 301–847–8615, email: *Rakesh.Raghuwanshi@fda.hhs.gov*.

Registration: If you wish to attend the symposium or view via Web cast, you must register at *http://www.fda.gov/medicalcountermeasures* by Tuesday, May 29, 2012, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

Dated: April 6, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–8695 Filed 4–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

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 for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 13, 2012, page 2072, and allowed 60 days for public comment. No public comments were received. 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 currently valid OMB control number.

Proposed Collection: Title: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil. *Type of Information Collection Request: Reinstatement* (OMB No. 0925–0597). *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 São 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) 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 will be enrolled for a 5-year period from March 2012 (or when OMB approval is received) 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 will be 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 will be asked to complete a confidential self-administered risk factor questionnaire by computer. In addition, a small blood sample will be collected from each HIV-positive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing will be 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 HIV 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.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Blood Donors 18 years old or older. The annual reporting burden is as follows: *Estimated Number of Respondents:* 100; *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:* 40. The annualized cost to respondents is estimated at: $260 (based on $6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated annual number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
100	1	0.40	40

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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, 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: 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 to: *glynnsa@nhlbi.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: March 27, 2012.

Keith Hoots,

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

Dated: March 30, 2012.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2012–8684 Filed 4–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute: 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Loan Repayment Grant Review.

Date: May 4, 2012.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, 301–435–0287, *carolko@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 4, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–8719 Filed 4–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Companion Diagnostics

Date: May 22, 2012

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals

Place: National Institutes of Health, 6116 Executive Boulevard, Room 707, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jeannette F Korczak, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8115, Bethesda, MD 20892, 301–496–9767, *korczakj@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 5, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–8721 Filed 4–10–12; 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; Retinal Biology and TBI in Developing Brain.

Date: April 27, 2012.

Time: 12 p.m. to 2 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: Samuel C. Edwards, Ph.D., IRG Chief, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Radiation Therapeutics.

Date: May 3, 2012.

Time: 1 p.m. to 3 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: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences Overflow.

Date: May 8, 2012.

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

Agenda: To review and evaluate grant applications.