DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Society of Clinical Research Associates—Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SoCRA).'' The public workshop regarding FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The public workshop will be held on May 21 and 22, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Indianapolis at Keystone Crossing, 8787 Keystone Crossing, Indianapolis, IN 46240, 317–846–2700.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $109.00 plus applicable taxes (available until April 20, 2014, or until the SoCRA room block is filled).

Contact: Myra K. Casey, Food and Drug Administration, 101 West Ohio St., Suite 500, Indianapolis, IN 46204, 317–226–6500, ext. 104; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *SoCRAmail@aol.com*.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SoCRA member, $575.00; SoCRA nonmember (includes membership), $650.00; Federal Government member, $450.00; Federal Government nonmember, $525.00; and FDA employee, free (fee waived).

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) Credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is accredited as a provider of CNE by the American Nurses Credentialing Center's Commission on Accreditation.

Registration instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to ''SoCRA''. Mail to: SoCRA (see *Contact* for address).

To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm*. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on registration, or for questions on the public workshop, contact SoCRA (see *Contact*).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements on related informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA: Why, When and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03583 Filed 2–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-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: 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** in Volume 78 on Friday, November 8, 2013, and page 67175, and allowed 60 days for public comment. One public comment was received that was a personal opinion regarding protecting the safety of the American blood donation system. 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.

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: NIH Desk Officer.

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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments 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.

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 respondents (participants). 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: February 3, 2014.

Keith Hoots,

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

Dated: February 6, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–03547 Filed 2–18–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Application—Neurosciences.

Date: March 4, 2014.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, (Teleconference), Rockville, MD 20852.

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.273, Alcohol Research Programs; National Institutes of Health, HHS).

Dated: February 12, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–03515 Filed 2–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications—Biomedical Sciences.

Date: March 10, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, (Teleconference), Rockville, MD 20852.

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.273, Alcohol Research Programs; National Institutes of Health, HHS)

Dated: February 12, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–03514 Filed 2–18–14; 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