academia to help bring additional products for clinical flow cytometry to market that are safe and effective.

In partnership with the National Institutes of Health (NIH) and National Institute of Standards and Technology (NIST), CDRH intends to utilize the findings of this workshop in the development of an appropriate, risk-based regulatory framework for Clinical Flow Cytometry, which promotes innovation and protects patient safety.

II. Topics

Topics for discussion during this workshop include: (1) Overview of Quality control and standardization issues associated with Clinical Flow Cytometry (FCM), including discussion of a NIST traceable standard; (2) Biological controls in Clinical FCM: The use of stabilized whole blood samples and cryopreserved cells for normals and chronic lymphocytic leukemia (CLL); (3) Third-party flow cytometry data analysis software; and (4) Overview of FDA regulation of Clinical FCM using the 510(k) clearance process.

The FDA is seeking representation from both North American and European clinical investigators at this workshop. This Clinical FCM Workshop is being planned to occur just prior to a CDER Workshop on the role of MRD in CLL which will be held February 27, 2013 (77 FR 76051, December 26, 2012). An FDA workshop for acute lymphocytic leukemia (ALL) MRD was held April 18, 2012, and a separate workshop on acute myelogenous leukemia (AML) MRD will be held March 4, 2013 (77 FR 76050, December 26, 2012).

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01419 Filed 1–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: The Jackson Heart Study (JHS)

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 the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 24, 2012, pages 65001–2, and allowed 60-days for public comment. No 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: The Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0491). *Need and Use of Information Collection:* This project involves annual follow-up by telephone of participants in the JHS study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. Recruitment of 5,500 JHS participants began in September 2000 and was completed in March 2004. 5,302 participants completed a baseline Exam 1 that included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, echocardiography, and pulmonary function. JHS Exam 2 began September 26 2005, followed by a more comprehensive Exam 3 that began in February 2009. The two new exams include some repeated measures from Exam 1 and several new components, including distribution of self-monitoring blood pressure devices. The continuation of the study allows continued assessment of subclinical coronary disease, left ventricular dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. The JHS Community Health Advisor Networks (CHANs) comprise another component of the study. The JHS data shows high prevalence of risk factors: 73% of recruited participants are hypertensive, 29% are diabetic, 56% are obese (BMI > 30kg/m2), and 30% have the metabolic syndrome. Exploration of the impact on and interaction of high risk factor levels with other measures of clinical and subclinical disease will help identify unique approaches through epidemiology and prevention research to reduce the disproportionate burden of CVD in African-Americans. . The JHS CHANs play an important role to address CVD prevention by providing training to community members to spread health promotion and prevention messages within the Jackson community. The JHS Community Health Advisors (CHAs) are trained and certified to organize and conduct various outreach activities in five Jackson-area communities. Data on the JHS CHAs will be collected. *Frequency of Response:* One-time. *Affected Public:* Individuals or households; Businesses or other for profit; not-for-profit institutions. *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 478; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response: 2.47);* and *Estimated Total Annual Burden Hours Requested:* 1253. The annualized cost to respondents is estimated at $24,206. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
Families	200	1	1/6	33
Physicians	200	1	15/60	50
Communities:				

ESTIMATE OF ANNUAL HOUR BURDEN—Continued

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
Bolton	16	10	90/60	240
Canton	14	10	90/60	210
Clinton	13	10	90/60	195
Jackson	15	10	90/60	225
Rankin	20	10	90/60	300
Total	478	.....	.....	1,253

Request for Comments: 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.

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: Ms. Cheryl Nelson, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number 301–435–0451 or email your request, including your address to: *NelsonC@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.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2013–01441 Filed 1–23–13; 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 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 on Aging Special Emphasis Panel; Circadian Clocks and Aging: Molecular Mechanisms.

Date: February 19, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites—Chevy Chase Pavilion, 4300 Military Rd. NW., Washington, DC 20015.

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Healthy Aging in Africa.

Date: February 28, 2013.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Jeannette Johnson, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7705, *johnsonj9@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Study of Elderly Sleep Cycle II.

Date: March 4, 2013.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Bita Nakahi, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7701 *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Drug Development for Alzheimer's Disease.

Date: March 27, 2013.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

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

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

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

Dated: January 17, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01329 Filed 1–23–13; 8:45 am]

BILLING CODE 4140–01–P