

biologics facility responded to a previous RSVP notice announced in the **Federal Register**, you should submit a request to participate in the program to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Lonnie Warren Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, e-mail: [matt@cber.fda.gov](mailto:matt@cber.fda.gov)

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to improve: (1) Its understanding of current industry practices, and regulatory impacts and needs; and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005, and through these annual notices, is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest, as well as

encouraging new interested parties to apply.

**II. RSVP**

*A. Regulatory Site Visits*

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example blood and tissue establishments. The visits may include packaging facilities, quality control and pathology/toxicology laboratories, and regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

*B. Site Selection*

All travel expenses associated with the site visits will be the responsibility of CBER; therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with CBER or another agency for which we have a memorandum of understanding.

Dated: January 11, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; The Framingham Study**

**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 November 6, 2007, page 62659, and allowed 60 days for public comment. Two 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, any 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 Framingham Study. *Type of Information Request:* Revision (OMB No. 0925-0216). *Need and Use of Information Collection:* The Framingham Study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third generation participants for the purpose of studying the determinants of cardiovascular disease. *Frequency of response:* Both individuals and physicians will be contacted annually. One response per contact per year is anticipated from physicians and informants; participants will average 1.49 responses to various components within each annual contact. *Affected public:* Individuals or households; businesses or other for profit; small businesses or organizations. *Types of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 5,569 and *Estimated Total Annual Burden Hours Requested:* 5,794.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Number of respondents	Average time per response	Annual hour burden
Individuals (Participants and Informants) .....	4719	1.107	5224
Physicians .....	850	0.671	570
Totals .....	5569	.....	5794

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and

clarity of the information to be collected; and (4) 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. Paul Sorlie, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10210, MSC # 7936, Bethesda, MD, 20892-7936, or call 301-435-0456 (non-toll-free number), or e-mail your request, including your address to: [SorlieP@NHLBI.NIH.GOV](mailto:SorlieP@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: January 8, 2008.

**Mike Lauer,**

*Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.*

Dated: January 8, 2008.

**Suzanne Freeman,**

*OMB Clearance Officer, NHLBI, National Institutes of Health.*

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**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. 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, Clinical Neuroscience and Disease.

**Date:** February 4-5, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Holiday Inn San Francisco-Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133.

**Contact Person:** Jerry L. Taylor, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301-435-1175, [taylorje@csr.nih.gov](mailto:taylorje@csr.nih.gov).

**Name of Committee:** Health of the Population Integrated Review Group, Behavioral Genetics and Epidemiology Study Section.

**Date:** February 7-8, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Doubletree Guest Sites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

**Contact Person:** Elisabeth Koss, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, (301) 435-1721, [kosse@csr.nih.gov](mailto:kosse@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Molecular Neurogenetics: Quorum.

**Date:** February 7, 2008.

**Time:** 8 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Grand Hyatt Washington, 1000 H Street, NW., Washington, DC 20001.

**Contact Person:** Robert C. Elliott, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301-435-3009, [elliottro@csr.nih.gov](mailto:elliottro@csr.nih.gov).

**Name of Committee:** Immunology Integrated Review Group, Cellular and Molecular Immunology—A Study Section.

**Date:** February 7-8, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.

**Contact Person:** Samuel C. Edwards, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, MSC 7812, Bethesda, MD 20892, (301) 435-1152, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Psychiatric Genetics.

**Date:** February 8, 2008.

**Time:** 8:30 a.m. to 9 a.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

**Contact Person:** Cheryl M. Corsaro, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435-1045, [corsaroc@csr.nih.gov](mailto:corsaroc@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, SMEP SBIR.

**Date:** February 10, 2008.

**Time:** 7:30 p.m. to 10 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

**Contact Person:** Richard J. Bartlett, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435-6809, [bartletr@csr.nih.gov](mailto:bartletr@csr.nih.gov).

**Name of Committee:** Oncological Sciences Integrated Review Group, Radiation Therapeutics and Biology Study Section.

**Date:** February 11-12, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Bo Hong, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, (301) 435-5879, [hongb@csr.nih.gov](mailto:hongb@csr.nih.gov).

**Name of Committee:** Oncological Sciences Integrated Review Group, Cancer Genetics Study Section.

**Date:** February 11-12, 2008.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

**Contact Person:** Zhiqiang Zou, PhD, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, (301) 451-0132, [zouzhiq@csr.nih.gov](mailto:zouzhiq@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Software Maintenance and Extension.

**Date:** February 11, 2008.

**Time:** 8:30 a.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Fairmont Washington, DC Hotel, 2401 M Street, NW., Washington, DC 20037.

**Contact Person:** George W. Chacko, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7849, Bethesda, MD 20892, 301-435-1245, [chackoge@csr.nih.gov](mailto:chackoge@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis panel, Neurotechnology: Quorum.

**Date:** February 12-13, 2008.

**Time:** 8 a.m. to 2 p.m.