

specific injury research that focuses on prevention and control.

**Matters To Be Discussed:** The meeting will include the review, discussion, and evaluation of individual research grant and cooperative agreement applications submitted in response to the Fiscal Year 2008 Funding Opportunity Announcement (FOA) CE08-001: Youth Violence Prevention Through Community-Level Change.

Agenda items are subject to change as priorities dictate.

**FOR FURTHER INFORMATION CONTACT:** J. Felix Rogers, Ph.D., M.P.H., Telephone (770) 488-4334, NCI/PC/ERPO, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, GA 30341.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 6, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E8-4945 Filed 3-11-08; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National Institute for Occupational Safety and Health (NIOSH) Education and Research Center, Program Announcement for Research (PAR) PAR06-485

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

**Time and Date:** 1 p.m.-2 p.m., March 17, 2008 (Closed).

**Place:** NIOSH, 2400 Century Parkway, NE., Atlanta, GA 30345, Telephone (866) 649-6988.

**Status:** The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**Matters To Be Discussed:** The meeting will include the review, discussion, and evaluation of "NIOSH Education and Research Center, PAR 06-485."

NIOSH determines that agency business requires its consideration of this matter on less than 15 days notice to the public and that no earlier notice of this meeting was possible.

**FOR FURTHER INFORMATION CONTACT:** M. Chris Langub, PhD., Scientific Review Officer, NIOSH, CDC, 2400 Century Parkway, NE., Atlanta, GA 30345, Telephone (404) 498-2543.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 6, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E8-4906 Filed 3-11-08; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0154]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the good laboratory practice (GLP) for nonclinical laboratory studies regulations.

**DATES:** Submit written or electronic comments on the collection of information by May 12, 2008.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Good Laboratory Practice (GLP) Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910-0119)—Extension**

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in humans and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and

conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include the following information: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by

persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies.

FDA estimates the burden of this collection of information as follows:

**TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>**

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) to (b)(6) and (c)	300	270.76	81,228	3.36	272,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a) to (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					786,308

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: March 6, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-4903 Filed 3-11-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection: Comment Request; Revision of OMB No. 0925-0002, exp. 10/31/08, "Ruth L. Kirschstein NRSA Individual Fellowship Application and Related Forms"**

**Summary:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection: Title:** Ruth L. Kirschstein NRSA Individual Fellowship Application and Related Forms. **Type of Information Collection Request:** Revision of a currently approved collection, OMB 0925-0002, Expiration Date 10/31/08. **Form Numbers:** PHS 416-1, 416-9, 416-5, 416-7, 6031, 6031-1. **Need and Use of Information Collection:** The PHS 416-1 and 416-9 are used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The other related forms (PHS 416-5, 416-7, 6031, 6031-1) are used by these individuals to activate, terminate, and provide for payback of a National Research Service Award. **Frequency of response:** Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed.

**Affected Public:** Individuals or households; businesses or other for-profit; not-for-profit institutions; Federal Government; and State, Local or Tribal Governments. **Type of Respondents:** Adult scientific trainees and

professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 34,454; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 4.1; and *Estimated Total Annual Burden Hours Requested:* 142,301. The annualized cost to respondents is estimated at: \$4,980,535. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**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.

**For Further Information Contact:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number 301-435-0941, or e-mail your request, including your address to: [curriem@od.nih.gov](mailto:curriem@od.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 3, 2008.

**George Gardner,**

*Assistant Grants Policy Officer, OPERA, OER, National Institutes of Health.*

[FR Doc. E8-4871 Filed 3-11-08; 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. 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, AIDS SBIR Biological Sciences.

**Date:** March 19-21, 2008.

**Time:** 6 a.m. to 3 p.m.

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

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

**Contact Person:** Kenneth A. Roebuck, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, [roebuckk@csr.nih.gov](mailto:roebuckk@csr.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.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Molecular Mechanisms of Neuronal Development and Regeneration.

**Date:** March 21, 2008.

**Time:** 4 p.m. to 7 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:** Lawrence Baizer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7850, Bethesda, MD 20892, (301) 435-1257, [baizerl@csr.nih.gov](mailto:baizerl@csr.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.

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

**Member Conflicts:** Cell Biology.

**Date:** April 8-9, 2008.

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

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