

sites after this document is published in the **Federal Register**.) Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the 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 related informed consent, clinical investigation requirements, institutional review board 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; (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 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: October 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24307 Filed 10–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 March 13, 2014 (Vol. 79, P. 14256) 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 Cancer Institute (NCI), 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.

DATES: *Comment 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: Margaret Mary Bertram, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., Rm 3W264, Rockville MD, 20850 or call non-toll-free number 240–276–5656 or Email your request, including your address to: *margaret.bertram@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR), 0925–NEW,

National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is a request for OMB to approve the Evaluation of National Institutes of Health (NIH) International Bilateral Programs for three years. The bilateral awards are made through the Funding Opportunity Announcement mechanism and administrative supplements, meaning they are funded by set-aside funds that are separate from the general pool of research program grant funds used to support investigator initiated research at NIH. The bilateral programs to be evaluated are the U.S.-China Program for Biomedical Research Cooperation, U.S.-India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Co-morbidities, U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and U.S.-South Africa Program for Collaborative Biomedical Research. These programs are funded and administered by various combinations of the following institutes: Fogarty International Center (FIC), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), and the Office of AIDS Research (OAR). While these programs differ, their underlying concept is the same; they require U.S. scientists to collaborate with scientists from other countries in order to conduct scientifically meritorious investigations of mutual interest to both countries. The proposed evaluation requests information about (1) accomplishments of the awards, (2) unique findings or opportunities due to the international collaborations, and (3) successes and challenges of these collaborations. The information will be collected one year into the award and at the end of the award, when possible. This information is needed to evaluate the effectiveness of these programs across NIH.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 129.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Principal Investigators	Administrative Supplements	24	1	1	24
	Year 1 Survey	52	1	1	52
	Final Year Survey	52	1	1	52
	Telephone Script for Non-Responders ..	16	1	3/60	1

Dated: October 6, 2014.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014-24437 Filed 10-10-14; 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; PAR:392: New Computational Methods for Understanding the Functional Role of DNA Variants that are Associated with Mental Disorder.

Date: October 29, 2014.

Time: 12:00 p.m. to 3:00 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: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046B, MSC 7892, Bethesda, MD 20892, 301-408-9655, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vascular Biology and Hematology AREA.

Date: November 6, 2014.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, pinkusl@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Child Psychopathology and Developmental Disabilities.

Date: November 10-11, 2014.

Time: 8:00 a.m. to 11:59 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301-435-0913, mark.lindner@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Mechanisms of Emotion, Stress and Health.

Date: November 10-11, 2014.

Time: 8:00 a.m. to 11:59 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301-435-0913, mark.lindner@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bacterial Biochemistry, Genetics, and Evolution.

Date: November 10, 2014.

Time: 2:30 p.m. to 4:30 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: Barbara J. Thomas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2218, MSC 7890, Bethesda, MD 20892, 301-435-0603, bthomas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small

Business: Non-HIV Anti-Infective Therapeutics.

Date: November 12, 2014.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Alexandria Old Town, 1456 Duke Street, Alexandria, VA 22314.

Contact Person: Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge, Rm 3204, MSC 7808, Bethesda, MD 20892, 301-496-6980, izumikm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA Application Review.

Date: November 12, 2014.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301-996-5819, zhengli@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cell Biology.

Date: November 12, 2014.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301-435-1191, ipws@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Imaging and Biomarkers for Early Cancer Detection: PAR13-189.

Date: November 12, 2014.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Chiayeng Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301-435-2397, chiayeng.wang@nih.gov.