

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or at <http://www.regulations.gov>.

Dated: September 21, 2001.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-24739 Filed 9-26-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Healthy Communities Study: How Communities Shape Children's Health (HCS)

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 has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 17, 2011, Pages 35452-3 and allowed 60 days for public comment. Three (3) 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: Healthy Communities Study: How Communities Shape Children's Health (HCS). **Type of Information Collection Request:** New. **Need and Use of Information Collection:** The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities conducted over five years that aims to (1) Determine the associations between community programs/policies and Body Mass Index (BMI), diet, and physical activity in children; and (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children. A total of 279 communities and over 23,000 children and their parents will be part of the HCS over the five-year study. A HCS community is

defined as a high school catchment area and the age range of children is 3-15 years upon entry into the study. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (e.g., school environment); measurements of children's physical activity levels and dietary practices; and children's and parents' BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research initiatives targeting childhood obesity. **Frequency of Response:** Varies by participant type from once to 2.74 times. **Affected Public:** Families or households; businesses, other for-profit, and non-profit. **Type of Respondents:** Parents, children, community key informants (who have knowledge about community programs/policies related to healthy nutrition, physical activity, and healthy weight of children), food service personnel, physical education instructors, state health department employees, and physicians or medical secretaries. The annual reporting burden is as follows: **Estimated number of respondents:** 247,619; **Estimated Number of Responses per Respondent:** 1.1; **Average (Annual) Burden Hours per Response:** 0.12; and **Estimated Total Burden Hours Requested:** 33,144. The annualized cost to respondents is estimated at \$434,789. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondents | Estimated number of respondents * | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested * |
|--|-----------------------------------|--|-----------------------------------|---|
| Parents/Caregivers (screening) | 169,650 | 1 | 0.17 | 9,614 |
| Parents/Caregivers | 20,358 | 1.46 | 1.14 | 11,295 |
| Second Parents/Caregivers | 10,179 | 1 | 0.12 | 407 |
| Parents/Caregivers who refuse to participate | 2,410 | 1 | 0.17 | 137 |
| Children | 20,358 | 1.46 | 0.78 | 7,728 |
| Key Informants (screening) | 4,820 | 1 | 0.08 | 129 |
| Key Informants | 3,615 | 2.74 | 0.85 | 2,806 |
| Food Service Personnel | 964 | 1 | 0.42 | 135 |
| Physical Education Instructors | 964 | 1 | 0.25 | 80 |
| State Health Department employees | 50 | 1 | 0.30 | 5 |
| Physicians/medical secretaries | 14,251 | 1 | 0.17 | 808 |
| Total | 247,619 | | | 33,144 |

* Estimated for first three years of the five-year study.

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, *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: Dr. Sonia Arteaga, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892-7936, or call non-toll free number (301) 435-0377 or e-mail your request, including your address to: *hcs@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: September 21, 2011.

Lynn Susulke,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael S. Lauer,

Director, DCVS, National Institutes of Health.

[FR Doc. 2011-24837 Filed 9-26-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 of Child Health and Human Development Initial Review Group, Health, Behavior, and Context Subcommittee.

Date: October 17, 2011.

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: Michele C. Hindi-Alexander, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-8382, *hindialm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-24855 Filed 9-26-11; 8:45 am]

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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, Academic Research Enhancement Award (Parent R15).

Date: October 11-12, 2011.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Rebecca Henry, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301-435-1717, *henryrr@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Pulmonary Fibrosis and Hypertension.

Date: October 12-13, 2011.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: George M Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, *barnasg@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Lung Development and Injury.

Date: October 18-19, 2011.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: George M Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, *barnasg@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 20, 2011

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-24841 Filed 9-26-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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.,