

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: January 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-450 Filed 1-12-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Follow-up of Kidney Cancer Patients From the Central European Multicenter Case-Control Study (CEERCC) (NCI)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), 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 November 3, 2008 (Volume 73, No. 213, p. 65387) and allowed 60 days for public comment. There was one public comment received which questioned why U.S. tax dollars are being spent on a study located in Europe. The investigator responded directly to the comment on 12/19/08 stating that this study costs less money to conduct in central Europe than in the U.S. since previous data has already been collected. Additionally, since this region has the highest rates of kidney cancer in the world a study in this area would provide a wealth of data in terms of the causes of kidney cancer. 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: Follow-up of Kidney Cancer Patients from the Central European Multicenter Case-Control Study (NCI). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this questionnaire is to obtain information on the 5-year survival status of kidney cancer patients that were previously enrolled in a Central European Case-Control Study of

Kidney Cancer that was conducted from 2001 to 2004. The aim is to assess survival, the prevalence of recurrent disease and progression, and to investigate patient, tumor and genetic determinants of survival among cases. The questionnaire will collect information on patient related factors, tumor related factors that were not collected during the initial study, and the type of treatment(s) received since the patients were last contacted for the case-control study. This questionnaire adheres to The Public Health Service Act, section 412 (42 U.S.C. 285a-1) and section 413 (42 U.S.C. 285a-2), which authorizes the Division of Cancer Epidemiology and Genetics of the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention and treatment. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Individuals that participated in the Central European Renal Cancer Case-Control Study between 2001-2004 and physician abstractors. The estimated total annual burden hours requested is 296. The annualized cost to respondents is estimated at \$5174. The data will be collected within a two-year period. There are no additional capital costs, operating costs, and/or maintenance costs to report.

ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (Minutes/Hour)	Annual burden hours
Patients	200	1	40/60	133.33
Families (NOK)	240	1	40/60	160.00
Physicians	10	1	15/60	2.50
Totals	450	295.83

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 Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Lee E. Moore, PhD, MPH, Investigator, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, Executive Plaza South, Room 8102, 6120 Executive Blvd., EPS-MS-7242, Bethesda, MD 20892-7270 or call non-toll-free number 301-496-6427 or e-mail your request, including your address to: moorele@mail.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 2, 2009.

Vivian Horovitch-Kelley,

*NCI Project Clearance Liaison Office,
National Institutes of Health.*

[FR Doc. E9-484 Filed 1-12-09; 8:45 am]

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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. Appendix 2), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Biological Testing Facility (RFP-NIH-NICHD-CPR-09-05).

Date: February 9, 2009.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5b01, Bethesda, Md 20892-9304, (301) 435-6680, skandasa@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: January 7, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-482 Filed 1-12-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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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 Special Emphasis Panel, Childhood Obesity RFA HD-08-023.

Date: February 6, 2009.

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: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver, National Institute For

Child Health & Development, 6100 Executive Boulevard, Room 5b01, Bethesda, MD 20812-7510, (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: January 7, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-483 Filed 1-12-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

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 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 Center for Research Resources Special Emphasis Panel; SEPA SEP.

Date: February 10, 2009.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lee Warren Slice, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, Bethesda, MD 20892, 301-435-0965.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)