

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

### Submission for OMB Review; Comment Request Clinical Trials Reporting Program (CTRP) Database (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 9, 2009, (Vol. 74, No. 215, p. 57684) and allowed 60-days for public comment. Two public comments were received. The first comment, received November 11, 2009, questioned the purpose and safety of clinical trials conducted outside of the United States. An e-mail response was sent on January 6, 2010, acknowledging the commenter's concern. The response noted that the NCI's Clinical Trials Reporting Program is an information collection activity intended to assist the NCI in management of the NCI's clinical trials portfolio, which is global in nature. The response further stated that while CTRP is not directly related to the conduct of a clinical trial, the NCI hopes to use the information to facilitate routine review of safety, efficacy, and

administrative data reported from ongoing cancer trials. On January 6, 2010, the same commenter sent a subsequent comment concerning corruption in clinical trials conducted by large pharmaceutical companies. The NCI sent an e-mail response on January 8, 2010, thanking the commenter for her additional comments and noting that they would be taken into consideration.

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: Clinical Trials Reporting Program (CTRP) Database. **Type of Information Collection Request:** REVISION of currently approved collection [OMB No. 0925-0600, expiration date 01/31/2010]. **Need and Use of Information Collection:** The NCI is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database, to serve as a single, definitive source of information about all NCI-supported clinical research, thereby enabling the NCI to execute its mission to reduce the burden of cancer and to ensure an optimal return on the nation's investment in cancer clinical research. Information will be submitted by clinical research administrators as

designees of clinical investigators who conduct NCI-supported clinical research. Deployment and extension of the CTRP Database, which will allow the NCI to consolidate reporting, aggregate information and reduce redundant submissions, is an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, Public Law 111-5 ("Recovery Act"). This information collection adheres to The Public Health Service Act, Section 407(a)(4) (codified at 42 U.S.C. 285a-2(a)(2)(D)), which authorizes and requires the NCI to collect, analyze and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country. **Frequency of Response:** Once per initial trial registration; four amendments per trial annually; and four accrual updates per trial annually. **Affected Public:** Individuals, Business and other for-profits, and Not-for-Profit institutions. **Type of Respondents:** Clinical research administrators on behalf of clinical investigators. The annual reporting burden is estimated at 38,500 hours (see Table below). There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

### A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS

| Type of respondents   | Survey instrument     | Number of respondents | Frequency of response | Average time per response (minutes/hours) | Annual burden hours |
|-----------------------|-----------------------|-----------------------|-----------------------|-------------------------------------------|---------------------|
| Clinical Trials ..... | Initial Registration. | 5,500                 | 1                     | 120/60                                    | 11,000              |
|                       | Amendment .....       | 5,500                 | 4                     | 60/60                                     | 22,000              |
|                       | Accrual Updates       | 5,500                 | 4                     | 15/60                                     | 5,500               |
| Total .....           | .....                 | 16,500                | .....                 | .....                                     | 38,500              |

**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 Attention: NIH Desk Officer, Office of

Management and Budget, at [OIRA\\_submission@omb.eop.gov](mailto: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 John Speakman, Associate Director for Clinical Trials Products and Programs, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH, DHHS, 2115 E. Jefferson Street, Suite 6000, Rockville, MD 20892 or call non-toll-free number 301-451-8786 or e-mail your request,

including your address to:  
[john.speakman@nih.gov](mailto:john.speakman@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 15, 2010.

**Kristine Miller,**

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

[FR Doc. 2010-1988 Filed 1-28-10; 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 and 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 Special Emphasis Panel; The Ontogeny of Infant Detection of Inauthentic Emotion/Emotional Memories in Children: Combining Behavior and ERP.

*Date:* February 25, 2010.

*Time:* 3:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Carla T. Walls, 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) 435-6898, [wallsc@mail.nih.gov](mailto:wallsc@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 25, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-1910 Filed 1-28-10; 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 and Human Development; Notice of Closed Meeting

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*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, Prenatal Events-Postnatal Consequences.

*Date:* February 25, 2010.

*Time:* 2:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Peter Zelazowski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892-7510, 301-435-6902, [peter.zelazowski@nih.gov](mailto:peter.zelazowski@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 25, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-1915 Filed 1-28-10; 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 and 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 Initial Review Group, Biobehavioral and Behavioral Sciences Subcommittee.

*Date:* February 24-25, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

*Contact Person:* Marita R. Hopmann, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435-6911, [hopmannm@mail.nih.gov](mailto:hopmannm@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 25, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-1917 Filed 1-28-10; 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.