

regarding their request to speak by January 11, 2008.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 10, 2008.

Randall W. Lutter,

Assistant Commissioner for Policy.

[FR Doc. E8-726 Filed 1-15-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Quality of Life Outcomes in Neurological Disorders

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Neurological Disorders and Stroke (NINDS), 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 September 24, 2007, page number 54269 and allowed 60 days for public comment. One public comment was received; also received were one request for the data collection plans and proposed instruments and a request for information on a related Web site. 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: Quality of Life Outcomes in Neurological Disorders; *Type of Information Collection Request:* New; *Form Number:* NA; *Need and Use of Information Collection:* In order to improve outcome

measurement in clinical trials of neurological conditions, NINDS is developing a health-related quality of life (HRQL) measurement system for major neurological diseases that affect the United States population. This measurement system must be consistent enough across the selected conditions to allow for cross-disease comparison, and yet flexible enough to capture condition-specific HRQL issues. The primary end users of this measurement system will be clinical trialists and other clinical neurology researchers; however the measurement system will also be appropriate for clinical practice. The proposed information collection will support psychometric testing of HRQL item banks and testing of Spanish translation of the final questionnaires. *Frequency of Response:* Once; *Affected Public:* Individuals; *Type of Respondent:* Adults and children. The annual reporting burden is shown in the following table. There are no Capital Costs, Operating Costs or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Adults	6,000	1	0.5	3,000
Children	3,000	1	0.5	1,500
Totals	9,000	4,500

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: Office of Management and Budget, Office of Regulatory Affairs, New Executive

Office Building, Room 10235, Washington, DC 20503, 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. Claudia Moy, Program Director, Clinical Trials Group, NINDS, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 2214, Bethesda, MD 20892, or call non-toll-free number 301-496-2789 or e-mail your request, including your address to: <moyc@ninds.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: December 20, 2007.

Joellen Austin Harper,

Executive Officer, NINDS, National Institutes of Health.

[FR Doc. E8-606 Filed 1-15-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Longitudinal Investigation of Fertility and the Environment Study

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 National Institute of Child Health and Human Development (NICHD), 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. This is a request for renewal of an information collection request that was approved (OMB Clearance 0925-0543) following publication in the **Federal Register** on January 9, 2004, page 1589 and December 2, 2004, page 70153.

Proposed Collection: Title: Longitudinal Investigation of Fertility and the Environment Study. *Type of*

Information Collection Request:
Renewal of OMB Clearance 0925-0543.

Need and Use of Information Collection: This study will assess the relation between select environmental factors and human fecundity and fertility. This research originally proposed to recruit 960 couples who are interested in becoming pregnant and willing to participate in a longitudinal study. Fewer than expected couples were enrolled during the first three years of the project (n=350), predominantly due to the fact that more couples were ineligible for participation than had been originally estimated. In light of this fact, the revised study plan is to enroll a total of 500 couples (i.e., 150 additional couples), a sample size that will not compromise the main study objectives. Fecundity will be measured by the time required for the couples to achieve pregnancy, while fertility will be measured by the ability of couples to have a live born infant. Couples who are unable to conceive within 12 months of trying or who experience a miscarriage also will be identified and considered to have fecundity-related impairments. The study's primary environmental exposures include: Organochlorine pesticides and polychlorinated biphenyls; metals; fluorinated compounds; phytoestrogens; and phthalates. A growing body of literature suggests these compounds may exert effects on human reproduction and development; however, definitive data are lacking serving as the impetus for this study. Couples will participate in a 20-30 minute baseline interview and be instructed in the use of home fertility monitors and pregnancy kits for counting the time required for pregnancy and detecting pregnancy. Blood and urine samples will be collected at baseline from both partners of the couple for measurement of the environmental exposures. Two semen samples from male partners and two saliva samples from female partners also will be requested. Semen samples will be used to assess male fecundity as measured primarily by sperm concentration and morphology. Saliva samples will be used for the measurement of cortisol levels as a marker of stress among female partners so that the relation between environmental factors, stress and human reproduction can be assessed. The findings will provide valuable information regarding the effect of environmental contaminants on sensitive markers of human reproduction and development, filling critical data gaps. Moreover, these

environmental exposures will be analyzed in the context of other lifestyle exposures, consistent with the manner in which human beings are exposed. *Frequency of Response:* Following the baseline interview, couples will each complete a five-minute daily diary on select lifestyle factors. Women will perform daily fertility testing and pregnancy testing at day of expected menses using a dipstick test in urine. Each test will require approximately five minutes for completion. This testing and diary reporting is required only up to the time women become pregnant, which on average should be in 2-3 months. Men will provide two semen samples, a month apart, requiring approximately 20 minutes for each collection, and women will collect two saliva samples, a month apart, requiring approximately five minutes. Participating couples will be given a choice to submit their information by mail or to send it electronically to the Data Coordinating Center. This option will be available throughout data collection in the event couples change their minds about how they would like to submit information. Bio-specimens will be collected by study participants and research nurses, where appropriate, and forwarded in prepaid delivery packages to the study's laboratories. *Affected Public:* Individuals from participating communities. *Type of Respondents:* Men and women aged 18-40 years. *Revised Estimated Number of Respondents:* 1,000. *Revised Estimated Number of Response Sets per Respondent:* 6 per women and 3 per men over approximately two years. *Average Burden Hours per Response:* .1947 for women and .31975 for men. *Revised Estimated Total Annual Burden Hours Requested:* 1,658 for women and 889 for men. The revised burden estimates represent a 48 percent reduction in the originally requested burden. There is no cost to respondents. 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) The necessity of the proposed collection of information for the proper performance of the function of the agency, including the practical utility of the information; (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 Dr. Germaine Buck Louis, Senior Investigator and Chief, Epidemiology Branch, DESPR, NICHD, NIH, 6100 Executive Blvd., Room 7B03, Rockville, Maryland 20852, or call non-toll-free number (301) 496-6155 or e-mail your request, including your address to: gb156i@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: January 3, 2008.

Paul Johnson,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. E8-609 Filed 1-15-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) (40 FR 22859, May 27, 1975, as amended most recently at 72 FR 57595, October 10, 2007, and redesignated from Part HN as Part N at 60 FR 56605, November 9, 1995), is amended as set forth below to reflect the transfer of the functions of the Chief Information Officer (CIO) from the Center for Information Technology (NU, formerly HNU) to the Office of the Director (NA, formerly HNA).

Section N-B, Organization and Functions, under the heading Center for Information Technology (NU, formerly HNU), is amended as follows:

(1) Replace the current section NU (formerly HNU) with the following:

Center for Information Technology (NU, formerly HNU). (1) Provides leadership for the determination of NIH computational and telecommunications needs at all levels and oversees the development of appropriate infrastructure support to meet identified