Estimated Total Annual Burden Hours: 540.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 14, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–5656 Filed 3–20–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Longitudinal Investigation of Fertility and the Environment

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request for renewal of an information collection request. The original information collection request was approved (OMB Clearance 0925–0543) following publication in the **Federal Register** on January 9, 2004, page 1589 and December 2, 2004, page 70153. The proposed collection extension was previously published in the **Federal Register** on January 16, 2008, page 2925 and allowed 60 days for public comment. Only one public comment was received during the previous comment period. It was received via e-mail from a concerned citizen who stated that she felt that the study should no longer continue because it is not a good use of tax dollars.

5 CFR 1320.5 (General Requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

Proposed Collection: Title: Longitudinal Investigation of Fertility and the Environment (LIFE Study). *Type of Information Collection Request:* EXTENSION (OMB control number 0925–0543, expiration date, March 30, 2008). *Need and Use of Information Collection:* The purpose of the LIFE Study is to assess the impact of environmental factors, broadly defined to include lifestyle factors, on human reproduction and development. The LIFE Study is consistent with the mission of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development that includes conducting basic, clinical and epidemiologic research focusing on factors and processes associated with human reproduction and development thereby, ensuring the birth of healthy infants capable of reaching full adult potential unimpaired by physical or mental disabilities. This study will assess the relation between select environmental factors and human reproduction and development. 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. Couples will be selected from geographic regions that were chosen from peer reviewed competitive proposals. 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. Infertility will be recognized for couples unable to conceive within 12 months of trying. The study's primary environmental exposures include: Organochlorine pesticides; polychlorinated biphenyls; polybrominated diphenyl ethers; metals; perfluorinated compounds; cotinine; and phytoestrogens. A growing body of literature suggests these compounds may exert adverse effects on human reproduction and development; however, definitive data are lacking especially for sensitive endpoints. Couples will participate in a 25-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 globally 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 such as use of cigarettes and alcohol, consistent with the manner in which human beings are exposed. *Frequency of Response:* Following the baseline interview (25 minutes), couples will each complete a 2-minute daily diary on select lifestyle factors. Women will perform daily fertility testing (7 minutes) approximately 11 days per cycle and pregnancy testing (4 minutes) at day of expected menses using a dipstick test in urine. Approximately 60% of women will become pregnant after 2 to 3 months, at which point they will switch to the less intensive portion of the protocol. 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 6 minutes each. 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. Study participants will collect semen and saliva samples and forward them in prepaid delivery packages to the study's

laboratories. Research nurses will collect blood and urine samples and return them to the study's laboratories. *Affected Public:* Individuals from participating communities. *Type of Respondents:* Men aged 18+ years and women aged 18–40 years. *Estimated Number of Respondents:* Approximately 500 couples enrolling (minimum of 400 completing the study). *Estimated Number of Response Sets Per Respondent:* 7 per woman and 4 per man over approximately two years. *Average Burden Hours Per Response:* (1) 0.17 hours for completing the screening instrument; (2) 0.42 hours for baseline interviews with men and women; (3) 2.5 hours for daily journal while attempting pregnancy for men and women; (4) 0.38 and 0.7 hours for biospecimen collection for women and men, respectively; (5) 2.6 hours for fertility monitors; (6) 0.27 hours for pregnancy testing for women; and (7) 0.29 hours for pregnancy journals for women. *Estimated Total Annual Burden Hours Requested:* 1,640 to 4,950 hours for female participants and 1,050 to 2,740 hours for male participants depending upon the length of time required for pregnancy. There is no cost to respondents. There are no Capital Costs, Operating Costs, and/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) 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. Germaine M. Buck Louis, Epidemiology Branch, Division of Epidemiology, Statistics & Prevention Research, NICHD, 6100 Executive Blvd., Room 7B03, Rockville, MD 20852, 301–496–6155. You may also e-mail your request to *louisg@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: March 12, 2008.

Paul L. Johnson,

Project Clearance Liaison, The Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. E8–5700 Filed 3–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Emergency Review; Comment Request; Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank

Summary: In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health hereby publishes notification of an Emergency Clearance for the expansion of the information related to the ''Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank.'' The expanded program will include information on certain clinical trials of drugs, biologics, and devices, whether or not they relate to serious and life-threatening diseases.

The information collection is essential to the mission of the FDA and National Institutes of Health [42 U.S.C. 282(j)(2)(A)(ii)] and is critical to meeting their roles in the Clinical Trial Registry that was expanded by Public Law 110–85, which was enacted on September 27, 2007.

NIH cannot reasonably comply with the normal clearance procedures for information collection, because the use of normal procedures will delay the collection and hinder the agency in accomplishing its mission and meeting new statutory requirements, to the detriment of the public good. Compelling reason exists for the collection of required information for successful planning and implementation of the expansion of the Clinical Trial Registry, as described in Public Law 110–85.

This information collection is essential to the effective stewardship of Federal Funds. After consultation with other agencies and NIH components, NIH has determined that the information is not currently available in any single, reliable, accessible source.

Proposed Collection: Title: Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank; Type of Information Collection Request: New; Form Number: NA; Need and Use of Information Collection: In compliance with provisions of Title VIII of Public Law 110–85 (Food and Drug Administration Amendments Act of 2007) the National Institutes of Health is modifying the clinical trial registry established under previous law [ClinicalTrials.gov, established in response to FDAMA, Section 113]. The registry collects specified information on certain clinical trials identified in the law, with the objective of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical trials, to the benefit of public health. The registry is widely used by patients, physicians, and medical researchers, in particular those involved in clinical research studies.

Public Law 110–85 expands the scope of clinical trials that must be registered in ClinicalTrials.gov to include certain defined clinical trials of drugs, biologics, and devices subject to FDA regulation, regardless of whether they are related to serious or life-threatening diseases. It also increases the clinical trial information (*i.e.*, number of data elements) that must be submitted as part of each registration.

Frequency of Response: Responsible parties for applicable clinical trials must submit the required information shortly after the initiation of a trial [by the later of 21 days after the first patient is enrolled or December 26, 2007]. Updates to registration records are thereafter required at least once a year, unless there are no changes to report. Changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. Records for trials that were ongoing (as defined in the Law) as of December 26, 2007 are also required to be updated to comply with the new registration data elements, even if they were previously registered.

Description of Respondents: Respondents are referred to in the law as ''responsible parties.'' The statute defines the responsible party as: (1) The sponsor of the clinical trial (as defined in 21 CFR 50.3) or (2) the principal