FR 58690), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0508. The approval expires on December 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: December 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request, Determinants of Male and Female Fecundity and Fertility

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.

Proposed Collection: Title: Determinants of Male and Female Fecundity and Fertility. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will assess the relation between select environmental factors and human fecundity and fertility. This research proposes to recruit 960 couples who are interested in becoming pregnant and willing to participate in a longitudinal study. 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. Biospecimens 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. *Estimated Number of Respondents:* 1,920. *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. *Estimated Total Annual Burden Hours Requested:* 3,183 for women and 1,706 for men. 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) 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.

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, 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 are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: December 30, 2003.

Ayesha Giles,

Project Clearance Liaison, NICHD, National Institutes of Health.

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