

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.

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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

needs; (2) develops, operates, and maintains a state-of-the-art regional computer facility and provides overall guidance based on legislation and policy that is responsive to the NIH mission; (3) establishes and operates the necessary organization and infrastructure to assure appropriate security, connectivity, and interoperability across the NIH Institutes and Centers (ICs), off-campus locations, and remote access; (4) collaborates on, and provides for, research activities in the computational biosciences and statistics; (5) develops, administers, and manages NIH systems, and provides consulting services to the ICs, in support of administrative and business applications; and (6) serves as a Federal Data Processing Center for administrative, biomedical, and statistical computing, provides data processing and high performance computing facilities and integrated telecommunications data networks, and provides services to the DHHS and other Federal agencies.

(2) Delete in their entirety the statements for *Office of the Deputy CIO (NU9, formerly HNU9)*; the *Information Technology Policy and Review Office (NU92, formerly HNU92)*, the *Information Security and Awareness Office (NU93, formerly HNU93)*; the *Information Technology Acquisitions Services Office (NU94, formerly HNU94)*; and the *Office of the Chief Information Technology Architect (NU19, formerly HNU19)*.

(3) *Section N–B, Organization and Functions*, under the heading *Office of the Director (NA, formerly HNA)*, is amended as follows:

Under the heading *Office of the Director (NA, formerly HNA)*, immediately following the statement for *Office of Portfolio Analysis and Strategic Initiatives (HNAU)* insert the following:

Office of the Chief Information Officer (NAV, formerly HNAV). (1) Advises the NIH Director on the strategic direction and management of significant NIH Information Technology (IT) program and policy activities; (2) provides leadership for the enhancement of NIH IT capabilities, scientific and research computing services, and enterprise systems through policies, guidelines and standards, budget management, and lifecycle performance monitoring; (3) directs the establishment of a common infrastructure that optimizes NIH's IT investments and that can adapt to emerging technologies and service models; (4) leads IT security initiatives to protect and secure NIH's information assets; (5) oversees the NIH-wide IT investment portfolio, inclusive of IC,

CIT, and enterprise systems; (6) approves the progress of enterprise projects through the DHHS Enterprise Performance Life Cycle (EPLC); (7) identifies critical IT issues and analyzes, plans, and leads NIH's implementation of special DHHS or Federal initiatives related to management of IT resources; (8) leads IT governance structure to align IT with NIH strategies and objectives; (9) leads the implementation of enterprise architecture policies, standards, and practices; (10) leads NIH IT support efforts on medical initiatives such as Electronic Health Record; and (11) provides leadership and focus within NIH for the development and implementation of policy and standards in IT by identifying, documenting, and communicating issues, problems, and solutions to the NIH community in a comprehensive way.

Information Technology Policy and Review Office (NAV2, formerly HNAV2). Advises and assists the NIH Chief and Deputy Chief Information Officers in managing NIH IT resources and investments through (1) development, implementation, and oversight of NIH IT policy and guidance; (2) interpretation and implementation of laws, regulations, and DHHS, Office of Management and Budget (OMB), and other Federal mandates; (3) development and oversight of IT capital planning and investment control activities; (4) coordination and preparation of IT budget and review documents; (5) development of IT management tools and training; and (6) provision of staff support to CIO committees and special initiatives, studies, and projects.

Information Security and Awareness Office (NAV3, formerly HNAV3). Provides guidance to the NIH Chief and Deputy Chief Information Officers regarding IT security, planning, and budget activities by (1) leading the development of program goals, policies, standards, and procedures for the NIH IT Security program; (2) providing guidance to ICs for security of information in accordance with the Privacy Act, the Computer Security Act of 1987, the Information Technology Management Reform Act (ITMRA), OMB, and DHHS guidance; (3) providing support to the NIH IT Management Committee (ITMC); (4) conducting NIH-wide IT security activities; (5) managing an NIH Incident Response Team; (6) managing an NIH Risk Management and Oversight Program; and (7) managing an NIH IT Security Awareness and Training Program.

Information Technology Acquisition Services Office (NAV4, formerly

HNAV4). Advises the NIH Chief and Deputy Chief Information Officers on IT contract expenditures and IT trends by (1) maintaining awareness of federally mandated laws, regulations, and standards as they relate to IT acquisition documents and IT investments; (2) participating in NIH-wide committees that impact NIH CIO initiatives, policies, and standards; (3) working closely with other ICs to ensure that NIH CIO initiatives and practices are reflected in IT submissions to DHHS and OMB; (4) assisting in the preparation of Statements of Work and supporting documentation such as schedules, evaluation criteria, and checklists required to implement the ITMRA, maintaining consistency with NIH/DHHS/OMB policies; (5) assisting NIH program managers in identifying appropriate mechanisms to satisfy their IT requirements, including NIH acquisition resources; and (6) advising NIH IT project managers on contract/task order management, administrative strategies, problem resolution, and techniques via meetings, e-mail, handbooks, and/or briefings.

Information Technology Architecture Office (NAV5, formerly HNAV5). (1) Advises the CIO on IT enterprise architecture for the NIH; (2) provides leadership to the development and management of an NIH enterprise architecture; (3) develops principles, policy, and technology standards to guide IT systems design and integration; (4) leads and/or evaluates enterprise projects and technologies for compliance and integration within IT architecture; (5) coordinates and represents IT enterprise architecture for the NIH; and (6) provides leadership, management, and implementation of transforming technologies for NIH such as Federal Public Key Infrastructure, Enterprise Application Integration Infrastructure, and Enterprise Identity Management Infrastructure, including the redesign of the NIH Enterprise Directory.

Delegations of Authority: All delegations and redelegations of authority to officers and employees of NIH which were in effect immediately prior to the effective date of this reorganization and are consistent with this reorganization shall continue in effect, pending further redelegation.

Dated: January 7, 2008.

Elias A. Zerhouni,

Director, National Institutes of Health.

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