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* 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 Nathaniel Rothman, Senior Investigator for the Occupational and Environmental Epidemiology Branch, Division of Epidemiology and Genetics, National Cancer Institute, 6120 Executive Boulevard, Room 8118, Rockville, MD 20892 or call non-toll-free number 301–496–9093 or email your request, including your address to: *rothmann @mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 15 days of the date of this publication.

Dated: February 13, 2012.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2012–3830 Filed 2–16–12; 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; New Proposed Collection; Comment Request Stress and Cortisol Measurement for the National Children's 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.

Proposed Collection

Title: Stress and Cortisol Measurement Substudy for the National Children's Study (NCS). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the Stress and Cortisol Measurement Substudy will develop an optimized, item-reduced measure of self-reported stress that is supported empirically through convergent validity analysis of stress biomarkers. Specifically, key moderators of stress biomarkers will be evaluated to inform the efficiency and quality of measurements during pregnancy. Development of a scientifically robust maternal stress measure would measure chronic stress more efficiently, would not require biospecimen collection and biomarker analyses, and would thereby reduce participant burden and NCS Vanguard (Pilot) and NCS Main Study costs. With this information collection request, the NCS seeks to obtain OMB's clearance to conduct a substudy aimed at developing a validated questionnaire that will reflect specific biological and physiological measures of maternal stress.

Background

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines ''environment'' broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (*http://www.hhs.gov/*) (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development (*http://www.nichd.nih.gov/*) and the National Institute of Environmental Health Sciences (*http://www.niehs.nih.gov/*) of the National Institutes of Health (*http://www.nih.gov/*) and the Centers for Disease Control and Prevention (*http://www.cdc.gov/*)), and the U.S. Environmental Protection Agency (*http://www.epa.gov/*).

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this information collection request, the NCS requests approval from OMB to perform a multi-center substudy, called the Stress and Cortisol Measurement Substudy. This substudy aims to

determine the most reliable, acceptable, and cost-efficient approach for assessing maternal stress. Maternal stress is of particular interest to the NCS due to studies that have shown an association between maternal stress and negative health outcomes, including preterm birth which is one of the most important problems in maternal-child health in the US. Stress factors are also more prevalent in the population of socio-demographically disadvantaged women who are at an increased risk for preterm birth. Maternal stress is associated with additional health outcomes, such as still-birth, low birth weight, problems in offspring brain function and behavior (including lower IQ and impaired executive function), immune-related problems such as allergies and asthma, congenital malformations, infections, and numerous disorders of organ systems.

Development of a scientifically robust and validated questionnaire to reflect specific physiological measures of stress would allow us to measure chronic stress more efficiently, would not require biospecimen collection and biomarker analyses, and would thereby reduce participant burden and Study costs. To develop this instrument, the NCS will collect several types of information from substudy participants through medical record abstraction, questionnaires (a series of validated stress measures), physiological measures (heart rate and self-reported stress), and several types of biospecimens.

Frequency of Response: Annual [As needed].

Affected Public: Pregnant women and their children.

Type of Respondents: Pregnant women who are not geographically eligible to enroll in the NCS Vanguard Study.

Annual Reporting Burden: See Table 1. The annualized cost to respondents is estimated at: $74,677 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, STRESS AND CORTISOL MEASUREMENTS

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours
Screening	Members of NCS target population (not NCS participants).	2,100	1	0.08	175
Consent	Members of NCS target population (not NCS participants).	700	1	0.17	117
Saliva Self-Collection Demonstration	Members of NCS target population (not NCS participants).	700	1	0.25	175
Urine Self-Collection Instructions	Members of NCS target population (not NCS participants).	700	1	0.08	58
Ecological Momentary Assessment Training.	Members of NCS target population (not NCS participants).	700	1	0.50	350
Visit 1 Stress Questionnaire	Members of NCS target population (not NCS participants).	700	1	1.00	700
Adult Blood	Members of NCS target population (not NCS participants).	700	2	0.50	700
Adult Urine	Members of NCS target population (not NCS participants).	700	1	0.25	175
Adult Hair	Members of NCS target population (not NCS participants).	700	2	0.25	350
Adult Saliva	Members of NCS target population (not NCS participants).	700	28	0.05	980
Demographic and Health Interview	Members of NCS target population (not NCS participants).	700	1	1.00	700
Participant Contact Information Sheet.	Members of NCS target population (not NCS participants).	700	1	0.08	58
Take-Home Questionnaire	Members of NCS target population (not NCS participants).	700	1	0.50	350
Time Diary	Members of NCS target population (not NCS participants).	700	72	0.03	1,680
Heart Monitoring	Members of NCS target population (not NCS participants).	700	1	0.03	23
Visit 2 Stress Questionnaire	Members of NCS target population (not NCS participants).	700	1	0.75	525
Stressful Life Events Schedule Checklist.	Members of NCS target population (not NCS participants).	700	1	0.50	350
Total		700			7,467

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 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

To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 496–1877 or Email your request, including your address to *glavins@mail.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: February 10, 2012.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2012–3809 Filed 2–16–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Selective Inhibitors of Polo-Like Kinase 1 (PLK1) Polo-Box Domains as Potential Anticancer Agents

Description of Technology: PLK1 is a regulator of cell growth that represents a new target for anticancer therapeutic development. High expression of PLK1 has been associated with several types of cancer (e.g., breast cancer, prostate cancer, ovarian cancer, non-small cell lung carcinoma). Inhibiting PLK1 could be an effective treatment for cancer patients without significant side-effects. Available for licensing are synthetic peptides with the ability to bind to polo-like kinase 1 (PLK1) polo-box domains (PBDs) with selectivity and nanomolar affinity and induce apoptosis in cancer cells. By inhibiting the functions of PLK1, these peptides could serve as potential anti-cancer therapies. This technology is related to and an extension of HHS technology reference E–181–2009.

Potential Commercial Applications:

- New anticancer therapies that specifically target PLK1.
- Platform for the development of further improved PLK1 inhibitors.

Competitive Advantages:

- High PBD binding affinity.
- High binding selectivity.

Development Stage: Early-stage.

Inventors: Terrence R. Burke, Jr. (NCI), et al.

Publications:

1. Liu F, et al. Serendipitous alkylation of a Plk1 ligand uncovers a new binding channel. Nat Chem Biol. 2011 Jul 17;7(9):595–601. [PMID 21765407]

2. Qian W, et al. Investigation of unanticipated alkylation at the N(pi) position of a histidyl residue under Mitsunobu conditions and synthesis of orthogonally protected histidine analogues. J Org Chem. 2011 Nov 4;76(21):8885–8890. [PMID 21950469]

Intellectual Property: HHS Reference No. E–053–2012/0—U.S. Provisional Application No. 61/588,470 filed 19 Jan 2012.

Related Technology: HHS Reference No. E–181–2009/3—U.S. Provisional Application No. 61/474,621 filed 12 Apr 2011.

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Influenza Vaccine

Description of Technology: It has been shown that the fusion peptide, a sequence comprised of fourteen amino acids at the N-terminal of the influenza hemagglutinin 2 protein is conserved among A and B influenza viruses. Monoclonal antibodies against this peptide are capable of binding all influenza virus HA proteins and inhibit viral growth by impeding the fusion process between the virus and the target cell. This application claims immunogenic conjugates comprising the fusion peptide region linked to a carrier protein. In preclinical studies, these conjugates were immunogenic and induced booster responses. The induced antibodies bound to the recombinant HA protein. This methodology of linking the highly conserved fusion peptide region to a carrier protein can broaden the protective immune response to include influenza A and B virus strains. This would eliminate the need for annual influenza vaccination.

Potential Commercial Applications:

- Influenza vaccines
- Influenza diagnostics
- Research tools

Competitive Advantages:

- Universal influenza vaccine
- Efficient manufacturing process
- May eliminate need for yearly influenza vaccination

Development Stage:

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Joanna Kubler-Kielb, Jerry M. Keith, Rachel Schneerson (NICHD).

Intellectual Property: HHS Reference No. E–271–2011/0—U.S. Provisional Application No. 61/541,942 filed 30 Sep 2011.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *ps193c@nih.gov.*

Collaborative Research Opportunity: The NICHD is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize conjugate influenza vaccines comprising fusion peptide region. For collaboration opportunities, please contact Joseph Conrad, Ph.D., J.D. at 301–435–3107 or *jmconrad@mail.nih.gov.*

ACSF3-Based Diagnostics and Therapeutics for Combined Malonic and Methylmalonic Aciduria (CMAMMA) and Other Metabolic Disorders

Description of Technology: Combined malonic and methylmalonic aciduria (CMAMMA) is a metabolic disorder in which malonic acid and methylmalonic acid, key intermediates in fatty acid metabolism, accumulate in the blood and urine. This disorder is often undetected until symptoms manifest, which can include developmental delays and a failure to thrive in children, and psychiatric and neurological disorders in adults. Once thought to be a very rare disease,