

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181 MSC 7846, Bethesda, MD 20892-7846, 301-435-1236, [zhaow@csr.nih.gov](mailto:zhaow@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Drug Related Small Business Review.

*Date:* February 14, 2014.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Yuan Luo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-915-6303, [luoy2@mail.nih.gov](mailto:luoy2@mail.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group, Chronic Dysfunction and Integrative Neurodegeneration Study Section.

*Date:* February 18-19, 2014.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301-435-1785, [kondratyevad@csr.nih.gov](mailto:kondratyevad@csr.nih.gov).

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Somatosensory and Chemosensory Systems Study Section.

*Date:* February 18-19, 2014.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Long Beach and Executive Center, 701 West Ocean Boulevard, Long Beach, CA 90831.

*Contact Person:* M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301-435-1766, [bennettc3@csr.nih.gov](mailto:bennettc3@csr.nih.gov).

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Bioengineering, Technology and Surgical Sciences Study Section.

*Date:* February 18-19, 2014.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Sheraton San Diego Hotel and Marina, 1380 Harbor Island Drive, San Diego, CA 92101.

*Contact Person:* Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301-435-2392, [masoodk@csr.nih.gov](mailto:masoodk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Cardiovascular Sciences.

*Date:* February 18, 2014.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Lawrence E. Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-8367, [boerboom@nih.gov](mailto:boerboom@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, PAR-11-100: Alzheimer's Disease Pilot Clinical Trials.

*Date:* February 18, 2014.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301-435-0913, [mark.lindner@csr.nih.gov](mailto:mark.lindner@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 16, 2014.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-01187 Filed 1-22-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Request for Information on the Proposed Framework for Developing Study Content and Protocols for the National Children's Study

**SUMMARY:** The National Children's Study (NCS) is soliciting comments and suggestions from the public on the proposed Study content framework. The questions solicited in this Request for Information (RFI) focus on the validity and acceptability of the using a composite outcome for the higher-level functions of a healthy 21-year-old person as an important operational construct to help frame data collection throughout the duration of the study.

Responses to this RFI will be used to inform Study protocol development.

**DATES:** The National Children's Study Request for Information is open for public comment for a period of 30 days. Comments must be received by February 24, 2014 to ensure consideration. After the public comment period has closed, the comments received by the NCS will be considered in a timely manner by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Children's Study.

**ADDRESSES:** Questions about this request for information should be directed to Kate Winseck, MSW, The National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5C01, Bethesda, MD 20891, [NCS\\_RFI@mail.nih.gov](mailto:NCS_RFI@mail.nih.gov), 301-594-9147.

**SUPPLEMENTARY INFORMATION:** The National Children's Study is a congressionally-mandated longitudinal birth cohort study intended to examine the effects of environmental exposures on the growth, development, and wellbeing of children. The NCS was mandated by the Children's Health Act of 2000 (Pub. L. 106-310).

#### 1. Goals and Requirements

The primary objective of the NCS is to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development. These factors include environmental exposures (with a broad definition of environment) and biological/genetic contexts. The Study objectives stated in the Children's Health Act of 2000 include: (1) Evaluate the effects of both chronic and intermittent exposures on child health and human development; (2) investigate basic mechanisms of developmental disorders and environmental factors; (3) 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; (4) gather data from diverse populations of children including prenatal exposures; and (5) consider health disparities among children.

#### 2. Proposed Study Content Framework

The NCS proposes to organize data collection priorities to support measurement of health and healthy development at critical stages. This requires understanding and identifying

known and potential factors that may influence health outcomes and characteristics along the developmental spectrum. For example, data collected during pregnancy are designed to look not only at antecedents of disease but also to look for factors associated with health. Which exposures are associated with a healthy, full term infant? What factors are predictive of a normal birth weight? What factors are associated with normal neurologic development? Areas that will be examined include, but are not limited to (1) physical factors such as maternal and paternal height, weight and Body Mass Index (BMI); (2) health behaviors such as sleep, diet and physical activity; (3) outcomes of past pregnancies and other medical conditions and history; (4) medication use (including alternative and complementary medicines); (5) presence or absence of components of the physical environment, such as noise, mold and mildew, pets, chemicals, and environmental tobacco smoke; and (6) psychosocial factors, such as social support, social networks, and psychological well-being and other factors that may protect and mediate reactions to stress. Biological and environmental samples will be collected to allow examination of in-utero exposures.

The NCS intends to follow all children from birth until they reach age 21, an endpoint consistent with the Food and Drug Administration Amendments Act of 2007 that defines "pediatric patients" as "those who are 21 years of age or younger at the time of diagnosis or treatment (FDA Amendments Act of 2007)." As such it is important to identify the characteristics of a healthy 21-year-old person. Reaching age 21 is one of many important developmental milestones and it serves as a useful life stage for illustration of how the NCS data collection framework can be organized.

To ensure the Study content framework is comprehensive, the NCS is working with subject matter experts to characterize health. As developmental trajectories are multi-dimensional, multi-directional, and multi-level, this effort not only helps characterize the distal end of the childhood developmental trajectory, but also identifies potential antecedent factors that could be measured earlier in life in assessing exposures that may contribute to later outcomes. For example, supportive family relationships during adolescence has been associated with positive outcomes ranging from reduced risk of poor mental health to higher levels of interpersonal and occupational functioning; these outcomes being

independent of any effect of gender, socioeconomic status, or family disruption, for example death or divorce (Child Adolescent Mental Health 16(1): 30–37).

At 21 years old, the thriving individual is a manifestation of complex, dynamic, non-linear developmental processes that are products of personal characteristics (including genetics), person-to-person, and person-to-environment interactions in the broadest sense. This characterization is consistent with the World Health Organization (WHO) construct (<http://www.who.int/hia/evidence/doh/en/>) which recognizes the following determinants of health:

- The social and economic environment
- The physical environment
- The person's individual characteristics and behaviors

A healthy 21-year-old person may possess such attributes as a BMI between 19 and 25, blood pressure about 120/80 mm mercury, sound mental health, and the ability to develop and maintain relationships with other people. A healthy 21-year-old person may be able to obtain employment if desired or circumstances warrant. A healthy 21-year-old person should be able to provide food, clothing, and shelter for themselves and, if desired or if circumstances warrant, for others. One would expect that a 21-year-old person would possess a solid foundation in literacy (including written and oral communication skills), numeracy, and problem solving skills. As young adults, they may have positive relationships with friends or family, a network of peers, and feel that they are part of a community. Furthermore, a healthy 21-year-old person is not defined on the basis of an individual who is free of disease or disability. If an individual has a limitation, she or he may still be able to function well, and even thrive, in society with the proper access to care, social support, and adaptations.

The NCS will measure health as well as the presence or absence of disease-related signs, symptoms, and limitations. This requires a data collection protocol that captures a full description of an individual—a health profile—rather than just known determinants of disease and subsequent outcomes. This is consistent with the Life Course Health Development model which "not only measures an individual's deficits but also calculates his or her health assets (The Millbank Quarterly 80(3): 433)."

As an organizing principle, the construction of a data collection approach around the characteristics of a healthy 21-year-old person allows the NCS to identify and measure the full range of experiences that may later influence individual outcomes. Measures must address the range of potential influences, from individuals, family, peers, the environment, communities or the larger society. This collection will supplement the conventional measurement of known or theorized antecedents of disease-related outcomes. The NCS does not intend to evaluate each participant using a particular paradigm as a preferred outcome, but rather to ensure that generally accepted health characteristics can be captured across the spectrum of the NCS. The NCS is not and cannot be a national screening program for various conditions but should be able to identify a wide range of phenotypic characteristics. The NCS will emphasize recording primary signs and symptoms, capacities and limitations, and a description of the whole person rather than diagnosing individuals as having particular diseases or conditions. Nonetheless, all relevant information from medical records, therapeutic interventions, and descriptions from participants and care takers will be captured and become part of the analytic data sets.

In such a model, however, the linking of a particular participant with a particular disease or condition may not offer all the necessary or even accurate information about either that individual or the population at large. By maintaining a focus on primary signs and symptoms, performance, any limitations, trends, developmental progress, experience, adaptation to changes in environment and context and relationships to the people and world around each participant, the NCS intends to maintain flexibility and precision for future analyses.

Health disparities will be addressed using a definition from the Centers for Disease Control and Prevention that notes disease burden, injury, violence, and health potential as key parameters (CDC, HHS, 2008). Each participant in the NCS will be evaluated for each of these parameters, regardless of any other demographic or socioeconomic characteristics. Through this approach, the NCS can maintain continuity of purpose through the ever-present changes in a dynamic society.

In sum, the NCS is proposing the use of a framework of distal outcomes, health determinants, primary signs and symptoms, phenotypic and environmental descriptions, and capture

of parameters associated with health disparities to guide the selection of the specific assessments along with their sequence and frequency. Related materials with additional information can be found here: <http://www.nationalchildrensstudy.gov/about/organization/advisorycommittee/Pages/January-2014-NCSAC-Meeting-Briefing-Book.aspx>.

### 3. Information Requested

This RFI invites the scientific community, health professionals, and the general public to provide comments and suggestions on the proposed framework of using the characteristics of a healthy, functional 21-year-old person, plus the other principles and factors noted, above for developing Study content and protocols. Given the requirements as stated in the Children's Health Act of 2000, please include in responses to the questions below whether the Study proposed content framework balances the complex requirements.

1. Please comment on the validity and acceptability of using a composite outcome—the higher-level functions of a healthy 21-year-old person—as an operational construct to help frame data collection.

2. Are there additional outcomes or developmental endpoints that should be considered?

3. What factors should the NCS use to prioritize assessments? Some examples of factors to consider are:

- a. Potential public health impact.
- b. Technical feasibility, including timing of data collection with regard to potential developmental vulnerability.
- c. Scientific opportunity to address knowledge gaps and illuminate developmental pathways.

This RFI is for planning purposes only and should not be construed as a solicitation for applications or proposals, or as an obligation in any way on the part of the United States Federal government. The Federal government will not pay for the preparation of any information submitted or for the government's use. Additionally, the government cannot guarantee the confidentiality of the information provided.

Dated: January 15, 2014.

#### Dean J. Coppola,

*Acting Director, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development.*

[FR Doc. 2014-01339 Filed 1-22-14; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Agency Information Collection Activities: Declaration of the Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day Notice and request for comments; Extension of an existing collection of information: 1651-0036.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Declaration of the Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (78 FR 69101) on November 18, 2013, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before February 24, 2014 to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, at 202-325-0265.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on

proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

**Title:** Declaration of the Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes.

**OMB Number:** 1651-0036.

**Form Number:** None.

**Abstract:** The Declaration of the Ultimate Consignee that Articles were Exported for Temporary Scientific or Educational Purposes is used to document duty free entry under conditions when articles are temporarily exported solely for scientific or educational purposes. This declaration, which is completed by the ultimate consignee and submitted to CBP by the importer or the agent of the importer, is used to assist CBP personnel in determining whether the imported articles should be free of duty. It is provided for under 19 U.S.C. 1202, HTSUS Subheading 9801.00.40, and 19 CFR 10.67(a)(3) which requires a declaration to Customs and Border Protection (CBP) stating that the articles were sent from the United States solely for temporary scientific or educational use and describing the specific use to which they were put while abroad.

**Current Actions:** CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

**Type of Review:** Extension (without change).

**Affected Public:** Businesses.

**Estimated Number of Respondents:** 55.