

**FOR FURTHER INFORMATION CONTACT:** *RoC Nominations:* Dr. Ruth Lunn, Director, OROc; telephone (919) 316-4637; [lunn@niehs.nih.gov](mailto:lunn@niehs.nih.gov). *OHAT Nominations:* Dr. Kristina Thayer, Director, OHAT, telephone (919) 541-5021; [thayer@niehs.nih.gov](mailto:thayer@niehs.nih.gov). Address for Dr. Lunn and Dr. Thayer: DNTP, NIEHS, 111 T.W. Alexander Drive, P.O. Box 12233, Research Triangle Park, NC 27709.

**SUPPLEMENTARY INFORMATION:** Request for Information: The NTP requests information on nine substances: Six substances have been nominated for possible review for future editions of the RoC (see <http://ntp.niehs.nih.gov/go/rocnom>) and three are under consideration by OHAT for evaluation of non-cancer health outcomes. (see <http://ntp.niehs.nih.gov/go/763346>). Specifically, NTP requests information on each substance regarding: (1) Data on current production, use patterns, and human exposure; (2) published, ongoing, or planned studies related to evaluating adverse health outcomes (e.g., cancer, development, reproductive, or immunological disorders); (3) scientific issues important for prioritizing and assessing adverse health outcomes; and (4) names of scientists with expertise or knowledge about the substance—please include any bibliographic citations when available. NTP will use this information in determining which substances to propose for formal health hazard evaluations.

#### **Six Substances Nominated for Possible Review for the RoC \***

##### *Flame Retardants*

- Pentabromodiphenyl ether mixture (DE-71)
- Tetrabromobisphenol A, CASRN 79-94-7

##### *Water Disinfection Byproducts*

- Dibromoacetonitrile, CASRN 3252-43-5
- Di- and tri-haloacetic acids (as a class); specifically, those haloacetic acids with similar functional or structural properties that may cause similar health hazards

##### *Other*

- Fluoride, CASRN 7681-49-4
- Vinylidene chloride, CASRN 5-35-4

\* Evaluations for the RoC may seek to list a new substance in the report, reclassify the listing status of a substance already listed, or remove a listed substance.

Three substances are being considered for OHAT evaluation of non-cancer health outcomes.

- Mountaintop removal mining (health impacts on surrounding communities)
- Neonicotinoid pesticides
- Fluoride (developmental neurotoxicity and endocrine disruption)

Information on RoC nominations should be submitted electronically on the OROc nomination page (<http://ntp.niehs.nih.gov/go/rocnom>) or by email to [lunn@niehs.nih.gov](mailto:lunn@niehs.nih.gov). Information on OHAT nominations should be submitted electronically on the OHAT nominated topics page (<http://ntp.niehs.nih.gov/go/763346>) or to [thayer@niehs.nih.gov](mailto:thayer@niehs.nih.gov). Public comments should include the submitter's name, affiliation, sponsoring organization (if any) along with appropriate contact information (telephone and email). Written information received in response to this notice will be posted on the NTP Web site, and the submitter identified by name, affiliation, and/or sponsoring organization.

Responses to this request for information are voluntary. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use. No proprietary, classified, confidential, or sensitive information should be included in your response.

Background Information on OROc: On behalf of NTP, OROc manages preparation of the RoC following an established, four-part process (<http://ntp.niehs.nih.gov/go/rocprocess>). The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called "substances") in our environment that pose a cancer hazard for people in the United States. Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. Newly reviewed substances with their recommended listing are reviewed and approved by the Secretary of Health and Human Services. The 13th RoC, the latest edition, was published on October 2, 2014 (available at <http://ntp.niehs.nih.gov/go/roc13>). The 14th RoC is under development.

Background Information on OHAT: On behalf of NTP, OHAT conducts literature-based evaluations to assess the evidence that environmental chemicals,

physical substances, or mixtures (collectively referred to as "substances") cause adverse non-cancer health outcomes. As part of these evaluations, NTP may also provide opinions on whether these substances might be of concern for causing adverse effects on human health given what is known about toxicity and current human exposure levels.

Dated: October 1, 2015.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Look AHEAD Brain MRI-2.

*Date:* December 1, 2015.

*Time:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 1, 2015.

**David Clary,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are 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 estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: National Outcomes Evaluation of the Garrett Lee Smith Suicide Prevention Program—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) is requesting clearance for the revision of data collection associated with the previously-approved cross-site evaluation of the Garrett Lee Smith (GLS) Youth Suicide Prevention and Early Intervention Program (GLS Suicide Prevention Program), now entitled National Outcomes Evaluation (NOE). The NOE is a proposed redesign of the currently-approved cross-site evaluation (OMB No. 0930-0286; Expiration, January 2017) that builds on prior published GLS evaluation proximal and distal training and

aggregate findings from program activities (e.g., Condrón et al., 2014; Walrath et al., 2015). As a result of the vast body of information collected and analyzed through the cross-site evaluation of the two GLS Suicide Prevention Programs components—the GLS State/Tribal Program and the GLS Campus Program—SAMHSA has identified areas for additional investigation and the types of inquiry needed to move the evaluation into its next phase.

The NOE aims to address the field's need for additional evidence on the impacts of the GLS Suicide Prevention Program in three areas: (1) Suicide prevention training effectiveness, (2) early identification and referral on subsequent care follow-up and adherence, and (3) suicide safer care practices within health care settings. The evaluation comprises three distinct, but interconnected core studies—Training, Continuity of Care (COC), and Suicide Safer Environment (SSE). The Training and SSE studies also have “enhanced” study components. Core study data align with required program activities across the State/Tribal and Campus programs and provide continuity with and utility of data previously collected (implementation and proximal outcomes). Enhanced components use experimental and quasi-experimental methods (randomized controlled trial [RCT] and retrospective cohort study designs) to truly assess program impacts on distal outcomes (e.g., identifications and referrals, hospitalizations, and suicide attempts and deaths) without undue burden on grantees and youth. This outcome- and impact-focused design reflects SAMHSA's desire to assess the implementation, outcomes, and impacts of the GLS program.

The NOE builds on information collected through the four-stage cross-site evaluation approach (context, product, process, and impact) to further the field of suicide prevention and mental health promotion. Of notable importance, the design now accounts for differences in State/Tribal and Campus program grant funding cycles (i.e., 5-year State/Tribal and 3-year Campus programs), while also establishing continuity with and maximizing utility of data previously collected. Further, the evaluation meets the legislative requirements outlined in the GLSMA to inform performance and implementation of programs.

Eleven data collection activities compose the NOE—two new instruments, three previously-approved instruments, and six previously-approved and improved instruments. As

GLS program foci differ by grantee type, some instruments will apply to either State/Tribal or Campus programs only. Of the 11 instruments, 2 will be administered with State/Tribal and Campus grantees (tailored to grantee type), 6 are specific to State/Tribal grantees, and 3 pertain only to Campus grantees.

#### Instrument Removals

Due to the fulfillment of data collection goals, six currently-approved instruments and their associated burden will be removed. The combined estimated annual burden for these instruments is 4,300 hours. These include the *State/Tribal Training Utilization and Preservation Survey*.

#### (TUP-S) Adolescent Version, Coalition Profile, and Coalition Survey, and the Campus Training Exit Survey (TES) Interview Forms, Life Skills Activities Follow-up Interview, and the Student Awareness Intercept Survey

#### Instrument Continuations

Three instruments will be administered only in OMB Year 1 to finalize data collection for the current cross-site evaluation protocol. Each instrument was previously approved as part of the four-stage approach (OMB No. 0930-0286; Expiration, January 2017) and no changes are being made. These include the *State/Tribal Referral Network Survey (RNS)*, *TUP-S Campus Version*, and *Campus Short Message Service Survey (SMSS)*. Each instrument will be discontinued once the associated data collection requirement has been fulfilled.

#### Instrument Revisions

Six currently-approved instruments will be revised for the NOE. Each of the instruments, or an iteration thereof, has received approval through multiple cross-site evaluation packages cleared by OMB. As such, the information gathered has been, and will continue to be, crucial to this effort and to the field of suicide prevention and mental health promotion.

- **Prevention Strategies Inventory (PSI):** The PSI has been updated to enhance the utility and accuracy of the data collected. Changes capture different strategies implemented and products distributed by grantee programs, the population of focus for each strategy, total GLS budget expenditures, and the percent of funds allocated by the activity type.

- **Training Activity Summary Page (TASP):** New items on the TASP gather information about the use of behavioral rehearsal and/or role-play and resources