

Approved: October 12, 2016.

Walter M. Shaub, Jr.,

Director, Office of Government Ethics.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2016-0093; NIOSH 248-F]

World Trade Center Health Program Scientific/Technical Advisory Committee (WTCHP STAC or Advisory Committee), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 9:00 a.m.–5:00 p.m., November 3, 2016 (All times are Eastern Daylight Time).

Place: Jacob J. Javits Federal Building, 26 Federal Plaza, New York, New York 10278. This meeting is also available by telephone and Web conference. Audio will be available by telephone only; visuals will be available by Web conference. The USA toll-free, dial-in number is 1-888-810-4931, and when prompted enter passcode—8328289. To view the web conference, enter the following web address in your web browser: <https://odniosh.adobeconnect.com/wtchpstac/>.

Public Comment Time and Date: 10:45 a.m.–11:15 a.m. (Eastern Daylight Time), November 3, 2016.

Please note that the public comment period ends at the time indicated above or following the last call for comments, whichever is earlier. Members of the public who want to comment must sign up by providing their name by mail, email, or telephone, at the addresses provided below by October 31, 2016. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first come—first served basis. Written comments will also be accepted from those unable to attend the public session.

Status: Open to the public, limited only by the number of telephone lines. The conference line will accommodate up to 50 callers. The room will accommodate approximately 100 persons.

Background: The Advisory Committee was established by Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111-347 (January 2, 2011), amended by Public Law 114-113 (Dec. 18, 2015), adding Title XXXIII to the Public Health Service Act (codified at 42 U.S.C. 300mm to 300mm-61).

Purpose: The purpose of the Advisory Committee is to review scientific and medical evidence and to make recommendations to the World Trade Center (WTC) Program Administrator regarding additional WTC Health Program eligibility criteria, potential additions to the list of covered WTC-related health conditions, and research regarding certain health conditions related to the September 11, 2001 terrorist attacks.

Title XXXIII of the PHS Act established the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors). Certain specific activities of the WTC Program Administrator are reserved to the Secretary, HHS, to delegate at her discretion; other WTC Program Administrator duties not explicitly reserved to the Secretary, HHS, are assigned to the Director, NIOSH. The administration of the Advisory Committee is left to the Director of NIOSH in his role as WTC Program Administrator. CDC and NIOSH provide funding, staffing, and administrative support services for the Advisory Committee. The charter was reissued on May 12, 2015, and will expire on May 12, 2017.

Matters for Discussion: The Advisory Committee will address the new responsibilities required under the reauthorization of the WTC Health Program in the PHS Act. Specifically, the enhanced role of the STAC to: (1) Make recommendations regarding the identification of individuals to conduct independent peer reviews of the evidence that would be the basis for issuing final rules to add a health condition to the List of WTC-Related Health Conditions; and (2) review and

evaluate the policies and procedures in effect within the WTC Health Program that are used to determine whether sufficient evidence is available to support adding a non-cancer condition or type of cancer to the List of WTC-Related Health Conditions.

The two policies can be found at: <http://www.cdc.gov/wtc/policies.html>.

The agenda will include workgroup presentations on independent peer review and the policies and procedures the WTC Health Program uses to add health conditions to the list of covered conditions.

The agenda is subject to change as priorities dictate.

To view the notice, visit <http://www.regulations.gov> and enter CDC-2016-0093 in the search field and click "Search."

Public Comment Sign-up and Submissions to the Docket: To sign up to provide public comments or to submit comments to the docket, send information to the NIOSH Docket Office by one of the following means:

Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS C-34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226.

Email: nioshdocket@cdc.gov.

Telephone: (513) 533-8611.

In the event an individual cannot attend, written comments may be submitted. The comments should be limited to two pages and submitted through <http://www.regulations.gov> by October 31, 2016. Efforts will be made to provide the two-page written comments received by the deadline above to the committee members before the meeting. Comments in excess of two pages will be made publicly available at <http://www.regulations.gov>.

Policy on Redaction of Committee Meeting Transcripts (Public Comment): Transcripts will be prepared and posted to <http://www.regulations.gov> within 60 days after the meeting. If a person making a comment gives his or her name, no attempt will be made to redact that name. NIOSH will take reasonable steps to ensure that individuals making public comments are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include a statement read at the start of the meeting stating that transcripts will be posted and names of speakers will not be redacted. If individuals in making a statement reveal personal information (e.g., medical information) about themselves, that information will not usually be redacted. The CDC Freedom of Information Act coordinator will, however, review such revelations

in accordance with the Freedom of Information Act and, if deemed appropriate, will redact such information. Disclosures of information concerning third party medical information will be redacted.

Contact person for more information: Paul J. Middendorf, Ph.D., Designated Federal Officer, NIOSH, CDC, 2400 Century Parkway NE., Mail Stop E-20, Atlanta, Georgia 30345, telephone 1 (888) 982-4748; email: wtc-stac@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-16PA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Study to Explore Early Development (SEED) Phase 3—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Autism spectrum disorders (ASD) are a group of neurodevelopmental disorders characterized by qualitative impairments in social interaction and communication and stereotyped behaviors and interests. Recent systematic population surveys and routine monitoring systems in the U.S. and other countries indicate the prevalence to be 1–2%. Apart from the identification of some rare genetic conditions that are commonly associated with autism, causal mechanisms for the disorder largely remain unknown.

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, and causes of autism and related developmental disabilities. Under the provisions of this act, NCBDDD funded five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) through program announcements in FY2001 and FY2002; CDC's NCBDDD served as the sixth CADDRE site.

For the first funding cycle (2001–2006), each CADDRE grantee had three core objectives: To develop a protocol for a multi-site collaborative epidemiologic study focused on autism (which was eventually named the Study to Explore Early Development [SEED]); to conduct surveillance of autism and other developmental disabilities; and to conduct site-specific investigator-

initiated studies on autism. In FY 2006, through a second CADDRE funding cycle, five grantees were awarded. The CADDRE activities for the second funding cycle (2006–2011) were limited to implementation of the first phase of SEED (subsequently known as SEED 1). CDC served as the sixth CADDRE SEED 1 site during this period. A second phase of SEED (SEED 2) was funded under a third funding cycle (2011–2016). Five CADDRE grantees received the awards. Again, CDC served as the sixth SEED 2 site.

A third phase of SEED (SEED 3) was funded in July 2016. Five extramural sites were funded. Together with the CDC, they will implement the SEED 3 collaborative protocol. The SEED 3 protocol for identification of study participants, recruitment, and study data collection flow will be similar to the protocols for SEED 1 and 2.

However, while all SEED phases have the same research goals and the same basic study design, data collection has been greatly streamlined and revised between SEED 1, SEED 2, and SEED 3. Many study instruments and data collection components included in the SEED 1 protocol are not included in the SEED 3 protocol; two instruments included in the SEED 3 protocol were developed subsequent to SEED 1 to capture an abbreviated version of information that had been included on some of the discontinued SEED 1 forms and to capture some additional information overlooked in the SEED 1 protocol; and instruments included in all phases of SEED underwent review and minor revision subsequent to SEED 1 to address ambiguities and difficulties experienced during SEED 1 data collection. Implementing this phase of SEED will increase the total SEED pooled sample size for investigation of high priority hypotheses. Maintaining the same basic study design and general protocol integrity will ensure that data pooling can be achieved across SEED phases.

Families will be identified from each of the 3 groups: Autism Spectrum Disorder (ASD), other developmental delay or disorder comparison group (DD), and a second comparison group of children randomly drawn from the entire study cohort population (POP). It is expected that the 6 SEED 3 study sites will have a total of 2,106 children enroll and complete the study protocol. The data collection process will take approximately 9 hours 10 minutes (ASD group); 5 hours 30 minutes (POP group); 2 hours 45 minutes (DD group) to complete, which includes (1) maternal telephone interview with questions about maternal reproductive history and