



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2023-0027, NIOSH-350]

World Trade Center Health Program; Youth Research Cohort; Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information; extension of comment period.

SUMMARY: CDC's National Institute for Occupational Safety and Health (NIOSH) is extending the public comment period for a request for information (RFI) that published April 26, 2023, regarding a World Trade Center (WTC) Health Program research cohort for future studies on health, social, and educational impacts among persons exposed to the September 11, 2001, terrorist attacks who were aged 21 years or younger at the time of their exposures. An organization interested in responding to the RFI asked CDC to extend the comment period to allow more time to submit comments. With this notice, the comment period is extended an additional 60 days, to allow interested parties additional time to respond.

DATES: Comments must be received by October 23, 2023.

ADDRESSES: Comments may be submitted through either of the following two methods:

- Federal eRulemaking Portal: <http://www.regulations.gov> (follow the instructions for submitting comments), or
- By Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS C-34, 1090 Tusculum Avenue, Cincinnati, Ohio 45226-1998.

Instructions: All written submissions received in response to this notice must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2023-0027, NIOSH-350) for this action. All relevant comments, including any personal information provided, will be posted without change to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Ave., MS C-46, Cincinnati, OH 45226; Telephone (404) 498-2500 (this is not a toll-free number); Email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION: The WTC Health Program was established by title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111-347, as amended by Pub. L. 114-113, Pub. L. 116-59, and Pub. L. 117-328, adding title XXXIII to the Public Health Service (PHS) Act (codified at 42 U.S.C. 300mm–300mm-62). All references to the Administrator in this document mean the Director of the NIOSH within CDC, or his or her designee.

The WTC Health Program conducts research among its members receiving monitoring or treatment in the Program and in sampled populations outside the New York City disaster area (NYCDA), as defined in section 3306(7) of the PHS Act, in Manhattan as far north as 14th Street and in Brooklyn.¹

In December 2022, the Consolidated Appropriations Act, 2023² amended section 3341 of the PHS Act to direct the Administrator, in consultation with the Secretary of Education, to establish a new research cohort. The cohort must be of sufficient size to conduct future research studies on the health and educational impacts of “exposure to airborne toxins, or any other hazard or adverse condition, resulting from the September 11, 2001, terrorist attacks, including on the population of individuals who were 21 years

¹ 42 U.S.C. 300mm–51.

² Pub. L. 117-328 (Dec. 29, 2022).

of age or younger at the time of exposure, including such individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.”³ The new WTC Health Program youth research cohort is referred to as “WTC Youth.” In accordance with section 3341, the cohort of WTC Youth must:

- Be of sufficient size to conduct future research studies on the health and educational impacts of 9/11 exposures;
- Include in this group sufficient representation of individuals who were 21 years of age or younger at the time of exposure; and
- Include in this group individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.

The cohort may also include individuals who were 21 years of age or younger on September 11, 2001, who were located outside the NYCDA and in Manhattan not further north than 14th Street; or anywhere within the borough of Brooklyn. Additionally, the cohort may include age-appropriate control populations as needed for research purposes.

In response to these new requirements, the Administrator, following consultation with the Secretary of Education, will engage the public for input on a multi-phased approach for establishing the youth cohort. At this time, the Administrator seeks initial comments on the following approach:

1. Phase I: Community Engagement: Gather sufficient information from educators, scientists, and community members on options for establishing a youth cohort that will efficiently support future research.
2. Phase II: Options Development: Use the information gathered in Phase I to develop a set of options for moving forward with establishing the youth cohort.

³ WTC survivors include individuals who lived, worked, went to school, or attended child or adult day care in the NYCDA on September 11, 2001, or in the following days, weeks, or months and those otherwise meeting the eligibility criteria in 42 CFR 88.7 or 88.8.

3. Phase III: Options Ranking: Engage community in ranking the options developed in Phase II.
4. Phase IV: Option Selection and Implementation: Use the information from Phase III to select the preferred option(s) for establishing the youth cohort.

Request for Information

In this request for information published in the *Federal Register* (88 FR 25406) on April 26, 2023, NIOSH is soliciting information from any interested party, including educators, researchers, clinicians, community members, WTC Health Program members, treatment providers, and government agencies at all levels (Federal, State, Territorial, local, and Tribal), regarding the proposed approach to establishing the WTC Health Program youth cohort.

In particular, NIOSH seeks comments on the following items regarding the general approach to assembling the cohort, as described above:

1. Whether the four-phased approach for establishing the youth cohort is comprehensive and adequately incorporates community involvement in selecting a preferred approach for establishing the youth cohort.
2. Any potential partnerships for future actions for establishing the cohort of WTC Youth.

NIOSH also seeks information on the following scientific parameters, best practices, and approaches for assembling a research cohort that is best suited for future research of WTC Youth:

3. Ideas regarding outreach, recruitment, retention, community involvement, and project oversight. NIOSH is interested in descriptions of any anticipated barriers to the project and propose potential risk mitigation strategies.

4. Health conditions and potential social and educational impacts (i.e., adverse effects of interest) that may be priorities for future research on WTC Youth. In light of these adverse effects to be researched, NIOSH is interested in descriptions of the cohort characteristics believed necessary to support future research, including recommendations on data collection requirements, such as describing methods for and frequency of contact with prospective cohort members.
5. The recruitment and retention of appropriate control group(s) for future observational studies of WTC Youth. For example, recruitment methods may differ between exposed and control groups given expected differences in participation rates. These differences may lead to a selection bias. A selection bias may also arise given the long period of time between exposure and recruitment (i.e., a survivorship bias). NIOSH is interested in comments regarding selection of controls using methods that reduce the potential for bias in future research.

Commenters are encouraged to offer information and insights into the specific topics described above, or any other aspect of this activity.

NIOSH received a request to extend the comment period from an organization interested in commenting on the RFI. CDC is extending the comment period to allow more time to comment. Accordingly, the comment period is extended through October 23, 2023.

Disclaimer

This notice is intended for planning purposes; it does not constitute a formal announcement for comprehensive applications. In accordance with Federal Acquisition Regulation 48 CFR 15.201(e), responses to this notice are not offers and cannot be

accepted by the Government to form a binding award. NIOSH will not provide reimbursement for costs incurred in commenting on this notice.

NIOSH will not respond to individual public comments or publish publicly a compendium of responses. An informational submission in response to this notice does not create any commitment by or on behalf of CDC or HHS to develop or pursue any program or ideas discussed.

John J. Howard,

*Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention,
Department of Health and Human Services.*

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