

Minutes

Meeting of the Scientific/Technical Advisory Committee (STAC) World Trade Center (WTC) Health Program



June 21-22, 2023

The World Trade Center (WTC) Health Program Scientific/Technical Advisory Committee (STAC) was convened for its 15th meeting on June 21, 2023, from 11:00 a.m. to 4:30 p.m., Eastern Daylight Savings Time (EDT), and on June 22, 2023, from 11:00 a.m. to 1:30 p.m., EDT. This was a virtual meeting conducted via Zoom. The public was welcome to follow the proceedings via live webcast on the World Wide Web. No registration was required.

Committee Members Present

Dr. Elizabeth Ward (chairperson)
Dr. Sophie Balk
Dr. John Comiskey
Ms. Chandra Davis
Dr. Joanna Gaitens
Dr. Mridu Gulati
Ms. Mariama James
Ms. Indrina Kanth
Dr. Michael Larrañaga
Dr. Debra Milek
Dr. Jason Ostrowe
Dr. Aarti Surti

Quorum was maintained throughout the meeting.

Public Comments

Twelve persons provided oral public comments via Zoom during the public comment periods that took place on June 21 from 1:45 pm to 2:15 pm, EDT, and on June 22 from 11:05 am to 11:35 am. In addition, written public comments were accepted and posted on the Federal eRulemaking Portal: <https://www.regulations.gov>.

Administrator's Opening Remarks

Dr. John Howard, Administrator of the WTC Health Program and Director of the National Institute for Occupational Safety and Health, welcomed the committee and announced the matters to be covered.

In December 2022, the Consolidated Appropriations Act, 2023 amended sec. 3341 of the Public Health Service (PHS) Act to direct the Administrator, in consultation with the Secretary of the U.S. Department of Education, to establish a new research cohort 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 of age or younger at the time of exposure, including such individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.”* The cohort may include individuals who were 21 years of age or younger on September 11, 2001, who were located outside the New York City Disaster Area (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.

The Administrator asked for advice from the STAC regarding:

1. A proposed four-phase approach for establishing the youth cohort, including the sufficiency of community involvement.
2. Potential partnerships for establishing the youth cohort.
3. Ideas regarding outreach, recruitment, retention, and project oversight; and
4. Anticipated barriers to forming a cohort that can adequately support future research studies, for example, representativeness, insufficient statistical power, information biases, and selection biases, and any potential strategies that address those barriers.

In addition, the Administrator requested the STAC's advisory recommendations and concurrence with the revised *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* to finalize it for implementation.

Finally, the Administrator asked the STAC for suggestions of peer reviewers for proposed additions to the List of WTC-Related Health Conditions.

Youth Cohort

Dr. Robert Daniels, Associate Director for Science of the WTC Health Program, explained the Administrator's proposed approach for establishing the youth cohort consisting of four phases:

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

Dr. Daniels also highlighted recent community engagement (Phase I) actions undertaken by the WTC Health Program:

- Request for Information published in the *Federal Register* on April 26, 2023, to solicit public input [[Docket No. CDC-2023-0027, NIOSH-350](#)].
- Development of a World Trade Center Health Program Youth Research Cohort, Request for Information [75D301-23-R-72680](#), published May 8, 2023.
- Published the [Youth Research Cohort](#) webpage June 6, 2023.

Dr. Joan Reibman, Professor in the Department of Medicine at the New York University Grossman School of Medicine and Medical Director of the H+H WTC Environmental Health Center, presented an Overview of Young Survivors. Dr. Reibman provided a brief description of the community of those exposed at a young age in the New York City Disaster Area and an overview of the WTC Environmental Health Center, the Survivor Center of Excellence in the WTC Health Program, and their experience with recruitment of young survivors. She described what is known and the gaps in knowledge about the population exposed at a young age in the WTC EHC. She also provided thoughts for recruitment and maintenance of the youth cohort including the use of Community Based Participatory Research (CBPR).

The WTC Health Program Survivors Steering Committee, led by Ms. Kimberly Flynn, introduced seven young survivors who provided testimony on their 9/11 experiences and their views on the development of the cohort. She also provided recommendations for recruitment and sustained engagement of members of the cohort.

Update on the Policy and Procedures for Adding Non-Cancer Conditions

Dr. Daniels presented an update to the revisions made to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* following the STAC's four recommendations at their meeting on February 9, 2023. The presentation detailed further

revisions made to the *Policy and Procedures* in response to recommendations of the STAC, as well as substantive changes that include additional descriptions of the Bradford Hill criteria used in the Science Team’s evaluation. Dr. Daniels explained that Section IV.A.1 of the previous *Policy and Procedures* addressed five criteria: strength, consistency, biological gradient, plausibility, and coherence. The proposed revision added descriptions for temporality, specificity, and analogy and explained why experiment was not listed.

Peer Review Update

Dr. Tania Carreón-Valencia, Senior Scientist at the WTC Health Program and Designated Federal Officer of the STAC, explained that according to the *Policy and Procedures* previously discussed, if the Administrator decides to propose adding a condition to the List of WTC-related health conditions, he will publish a Notice of Proposed Rulemaking (NPRM) in the Federal Register. The NPRM will solicit comments from the public. Also, the Administrator will conduct an independent peer review of the Program’s evaluation of scientific and technical evidence supporting the addition of the condition. The peer reviewers will be asked to review the evaluation of the evidence for the condition to the List within the context of the policy and provide a brief written report.

She requested suggestions from the STAC of subject matter experts that can conduct these peer reviews. One suggestion was received during the meeting, and others could be submitted to Dr. Carreón-Valencia via email.

Committee’s Deliberations

Following questions and deliberation, all members present agreed to the following recommendations regarding the Youth Cohort:

Ideas regarding outreach, recruitment, retention and project oversight:

The STAC recognizes that there may be several phases of outreach. Several speakers described the sense of isolation they have experienced as a childhood survivor of 9/11 and others noted a lack of awareness of the World Trade Center Health Program among survivors in younger age groups. Survivors who have left the NYC area and are not otherwise in touch with 9/11 survivors and organizations may be the most difficult group to recruit. The Program may wish to consider a broad outreach campaign to raise public awareness of benefits available to survivors with covered conditions and plans for the Youth cohort study.

The STAC recognizes that at this point it is unclear whether the cohort will be self-identified (with verification) or based on a sampling frame such as NYC Board of Education Records (BOE records), or a combination of both. The STAC believes it is important to use additional

sources other than the BOE given that BOE records will include only those in the public school system and not residents in private schools and those who are too young to be in school. To ensure that all these groups are represented in the Youth cohort, it will be critical to conduct multi-faceted national outreach using methods tailored to the communication preferences of the targeted age groups, such as using social media campaigns. In addition, it will be important to identify and utilize existing networks such as alumni associations through which recruitment can be facilitated. To ensure the representativeness of the cohort, it will be important to consider cultural diversity by including community leaders of ethnically and racially diverse groups in outreach and recruitment efforts.

If recruitment is done using a sampling frame such as BOE, experience has shown that it is difficult to get response/participation using traditional recruitment methods. Several options to facilitate recruitment were discussed, including use of communication tools targeted to the relevant age groups (social media, text messaging) and leveraging existing stakeholder partnerships, both local and national. Lessons learned can be derived from experience with COVID and long-Covid affected persons where digital platforms have been leveraged to conduct outreach, education, and recruitment. Since understanding the health effects of 9/11 exposures in this population will require ongoing follow-up, long-term retention will be critical. One suggestion is for the Program to facilitate online opportunities for survivors to communicate with each other, as well as regular communication regarding study findings and activities. This could be done by partnering with existing stakeholder organizations. The STAC believes that offering compensation for the time and effort of participating will be critical to recruitment and retention.

The STAC discussed the possibility of offering medical screening or testing as an incentive for participation. While we recognize that such an offering might encourage some survivors to participate and offers the possibility of early detection and treatment of WTC-related conditions, it would be premature to make a recommendation without knowing the nature of the screening and careful evaluation of potential risks and benefits.

Anticipated barriers to forming a cohort that can adequately support future research studies, for example, representativeness, insufficient statistical power, information biases, and selection biases, and any potential strategies that address those barriers:

The STAC acknowledges that all of these issues are of concern. If the cohort is self-identified, there will not be a sampling frame from which participation rates can be calculated. If there is, at least in part, a sampling frame such as Board of Education records, it would be possible to determine participation rates among those successfully contacted. In general, when participation rates are low or unknown, there is always concern, from an epidemiologic perspective, as to whether those who agreed to participate did so because they are more likely to have the health condition under study. Given how early it is in the planning for the study, it is difficult for the STAC to suggest strategies to address these barriers, beyond those already mentioned in the context of recruitment and retention.

Inclusion of those with in-utero exposures in the youth cohort:

In addition to the issues outlined in the charge, the STAC supports the inclusion of youth whose 9/11 exposure occurred in utero. Prior research has found evidence of lower birth weight and other adverse outcomes among children of women who lived near the World Trade Center during pregnancy, with a stronger effect among those with first trimester exposure. There is also evidence that environmental contaminants may pass from the mother to the fetus and that maternal traumatic experiences during pregnancy may affect the fetus. Given the level of resources projected to be available for the Youth Cohort, this may be the only opportunity to investigate the impact of in-utero exposure in a large and representative sample.

In addition, members of the Committee voted (with one abstention) to accept the revisions to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*.

Certification Statement

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the June 21-22, 2023, meeting of the World Trade Center Health Program Scientific/Technical Advisory Committee (STAC) are accurate and complete.

A handwritten signature in cursive script that reads "Elizabeth Ward".

Elizabeth Ward, PhD
Chair, STAC