

# Minutes

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



September 23, 2024

The World Trade Center (WTC) Health Program Scientific/Technical Advisory Committee (STAC) was convened for its 16th meeting on September 23, 2024, from 11:00 a.m. to 3:00 p.m., Eastern Daylight Savings Time (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. John Comiskey  
Dr. Joanna Gaitens  
Dr. Mridu Gulati  
Ms. Mariama James  
Dr. Anita Jose  
Ms. Indrina Kanth  
Dr. Alya Khan  
Dr. Michael Larrañaga  
Dr. Michele Marcus  
Dr. Steven Markowitz  
Dr. John Meyer  
Dr. Jason Ostrowe  
Dr. Aarti Surti  
Dr. Glenn Talaska

Quorum was maintained throughout the meeting.

### Public Comments

Six persons provided oral public comments via Zoom during the public comment period that took place on from 1:15 pm to 1:45 pm, EDT. 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 extended a warm welcome to its two new members, Dr. Alya Khan and Dr. Michele Marcus. He also announced the matters to be covered.

The Administrator introduced CAPT Lisa Delaney, MS, CIH who has served as the Director of the Division of the World Trade Center (WTC) Health Program and Deputy Administrator of the Program since February 20, 2024.

He announced an update on the Program's research portfolio, including initiatives that the Program has undertaken to communicate research findings, funding opportunities, and webinars and meetings, as well as efforts to increase the number of members that consent for participation in research projects.

The Administrator thanked the Committee for their previous advice regarding the Youth Cohort project timeline and available resources, ensuring effective communications and the need for broad outreach, and the inclusion in the cohort of persons who may have received 9/11-exposure while *in utero*. He announced that details on the Program's progress in establishing this cohort would be provided.

He also indicated that the National Defense Authorization Act (NDAA) for Fiscal Year 2024 amended the Zadroga Act to expand eligibility for Pentagon and Shanksville responders to include certain active duty, retired, or reserve members of the military, civilian employees of the Department of Defense (DOD) or other Federal agencies, and certain DOD or Federal contractors who responded to the Pentagon or Shanksville sites. He announced that details on the eligibility criteria and regulatory changes that have been made to implement the new law would be provided.

The Administrator informed of non-substantive changes made to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*. He indicated that an update would be provided for informational purposes only.

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

## **WTC Health Program Research Update**

Dr. Travis Kubale, Associate Director for Research Integration of the WTC Health Program, provided an overview of ongoing web-based features and initiatives designed to provide

access to a range of World Trade Center research, information, and resources, and to support efforts to identify research gaps and needs, and to inform research funding opportunities. He informed that the WTC Health Program eNews system, currently keeps over 15,000 researchers, enrollees, and stakeholders informed about a variety of research activities, including the release of publications, awarded research projects, monthly research webinars, biannual research meetings, and research funding opportunities. He also indicated that the Research webpage is updated regularly and provides a range of resources including searchable dashboard libraries cataloguing all WTC research publications and funded projects, recorded research webinar and research meeting presentations. The WTC Health Program Publication Library is a comprehensive catalog of over 1,300 WTC research publications and users can focus article searches by using a variety of filters. Users can access abstracts for each publication by clicking the publication title. The Research webpage also features the Youth 9/11 Health Effects Library, that includes 195 peer-reviewed publications examining the health effects of this population. The dashboard is designed as a resource to support initiatives to establish a youth cohort, and for those examining the long-term health effects of this population.

Dr. Kubale indicated that for Fiscal Year 2026 the Program plans to have a separate U01 research cooperative agreement solicitation examining and focusing exclusively on emerging health conditions related to the WTC Health Program. Regarding 2024 awarded research grants, he pointed out that the selection reflects a mix of high-impact projects that focus on key areas of need in the research portfolio. Emerging conditions include cardiovascular diseases and Alzheimer disease. Enhanced surveillance is included, cancer risk among survivors, and a variety of intervention projects that focus on medication use, asthma self-management, and mental health symptom reduction among a predominantly Hispanic population. He mentioned upcoming research events, including the research webinar on October 10, 2024, and the semiannual research meeting on November 13, 2024, in New York City, that will include in-depth discussions and presentations on the state of the Program's cardiovascular disease research.

Finally, Dr. Kubale informed of an initiative regarding member consent and participation in research projects. He indicated that consenting by the Clinical Centers of Excellence began pre-Zadroga and is ongoing. The requirement for consenting at the William Street clinic and the National Provider Network (NPN) was included in the latest round of Data Center contracts enacted in 2022 to provide easier access to consent for those populations. Under the contract, the General Responders Data Center is responsible for consenting NPN responders, and consenting for this group just began in February of this year. The Survivor Data Center is responsible for consenting NPN survivors and individuals at the William Street clinic. Consenting for the NPN survivors is planned to begin this fall, in 2024.

Consenting for the William Street clinic members began in February of 2023. He presented information on the status of the consent initiative.

### **Youth Research Cohort Update**

Dr. Robert Daniels, Associate Director for Science of the WTC Health Program, provided an update on the development of the Youth Research Cohort. He explained that upon the STAC recommendation in June of 2023 to include persons who were exposed prenatally, and after considerable scientific, legal and policy review, the Program determined that the Cohort can and should include persons exposed while *in utero*. He also informed the Committee that the Program has begun the development of a secure web portal for the collection of names, contact information, ages, exposure, and other protected information that would be needed for self-enrollment into the Youth Research Cohort. This portal would support consent for future research, would allow for a bidirectional communication between the Program and study participants, and would allow provisions to opt out of the cohort at any time. He also indicated that upon approval of the Office of Management and Budget (OMB), it is expected that the Youth Research Cohort registration portal will be functional and recruiting members in the spring of 2025. He also informed the Committee that the Program has been in contact with the National Center for Education Statistics at the US Department of Education, who are facilitating contact with the New York City Department of Education to obtain necessary lists to develop a sampling frame.

Questions for Dr. Daniels focused on eligibility and outreach. One member asked if responders' children are eligible to enroll in the cohort because of take-home exposures, but Dr. Daniels indicated that they are currently not considered to form part of the Youth Cohort; furthermore, they are not eligible to be members of the WTC Health Program. Regarding outreach, Dr. Daniels informed the Committee that a collaborative effort is underway, wherein RAND Corporation will help develop two-way communications between community members and organizations and the Program through co-learning sessions, webinars, and in-person focus group activities. This effort is planned to begin at the start of 2025. Other issues that arose during discussion included leveraging the extensive networks that already exist to recruit people and the use of Community-Based Participatory Research in these efforts. Dr. Daniels acknowledged the need for better communication regarding the ongoing cohort development progress.

## **Expansion of Program Enrollment Eligibility for Pentagon and Shanksville Responders**

Ms. Catharine Hilaker, Policy Analyst and Government Affairs Liaison of the WTC Health Program, informed the Committee on the expansion of program enrollment eligibility for Pentagon and Shanksville responders. She explained that at these sites, the Zadroga Act allowed enrollment into the WTC Health Program for those who were members of a fire or police department, which included fire or emergency personnel, active or retired; worked for a recovery or cleanup contractor, meaning they were hired specifically for cleanup purposes; or were volunteers. They had to have performed rescue, recovery, demolition, debris cleanup, or other related services. The National Defense Authorization Act (NDAA) expanded the Zadroga Act to add three additional categories to the responders at Pentagon and Shanksville. These categories included employees of the Department of Defense or any other federal agency, contractors of the Department of Defense or any other federal agency, and members of a regular or reserve component of the uniformed services. The NDAA provided funding of \$232 million to pay for the healthcare benefits of this group, and the enrollment is capped at 500 individuals. To make this legislation effective, the Program published an Interim Final Rule on September 11, 2024. It is estimated that potentially 8,500 individuals responded at the Pentagon site and that 1,000 individuals were present at the Shanksville crash site. While the Interim Final Rule went through clearance, the Program worked to update the internal and external software systems to be able to identify who can be enrolled as an NDAA expanded responder. Because of the funding provided in the legislation to pay for this group's healthcare benefits is specific to this group, it is necessary to ensure that they are correctly identified and that their bills are correctly processed. She mentioned that the Program continues to review all previously received Pentagon and Shanksville applications and that 40 people were identified and immediately enrolled under the new rule on September 11, 2024.

In response to a member question regarding the cap on enrollment, Ms. Jessica Bilics, Policy Analyst and Government Affairs Liaison of the WTC Health Program, indicated that there is also a statutory limitation for the enrollment of new responders and newly certified survivors since the enactment of the Zadroga Act, and it also had a requirement of notifying the Secretary of the Department of Health and Human Services when enrollment hit 80%. When that happened, there was congressional action, and they increased the statutory limitation. It is possible that there could be congressional action taken when enrollment hits 400 for the NDAA expanded group.

## **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*. These revisions were considered non-substantive by counsel, and include section I.B., which is a list of definitions. These definitions came primarily from other Program documents and were originally referenced in footnotes. Further clarification was provided in section III.B on the literature search and included examples of searched databases and acknowledgment that the keyword search is under the judgment of the Science Team doing the evaluation. Under section IV.A.1. the Program clarified that although the Science Team relies on studies of the 9/11-exposed population for their assessment of a causal relationship, issues of biological plausibility, coherence, and analogy are outside the focus of 9/11 research. Therefore, it is now specifically stated that the Science Team goes outside of the 9/11 body of literature to understand biologic plausibility. Dr. Daniels explained that the Science Team has always considered study limitations as part of their weight of evidence assessment, but it was not explicitly stated in the *Policy and Procedures*, but it is now under Section IV.A.3.

In response to a question from a member, Dr. Daniels informed the Committee that there are several valid petitions under evaluation. These include cardiovascular, cerebrovascular, and immune systems. Disease entities include amyotrophic lateral sclerosis, anti-glomerular basement membrane (anti-GBM) disease, extrapulmonary sarcoidosis, hepatic steatosis, Parkinson disease, peripheral neuropathy, and persistent hearing loss. There is a backlog, and the Program is working through it. The Program is also working on better documenting the evaluation process, study limitations, and decisions that are being made with respect to causality. Other questions regarding language in the *Policy and Procedures* were also addressed.

## **Peer Review Update**

Dr. Tania Carreón-Valencia, Senior Scientist of 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. She indicated that suggestions could be submitted via email at any time.

### **Administrative issues and closing remarks**

Dr. Carreón-Valencia thanked all attendees, the public commenters, and those at NIOSH that made the meeting possible. She invited members to follow the WTC Health Program Research website, the Youth Cohort website, and the STAC website, and to attend the Research webinars.

### **Certification Statement**

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the September 23, 2024, 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