WTC Health Program's Survivors Steering Committee
Public Comments to WTC STAC February 9, 2023
Re: Draft Policy and Procedures for Adding Non-Cancer Health Conditions
to the List of WTC-Related Health Conditions

I am Kimberly Flynn, and I am speaking on behalf of the WTC Health Program's Survivors Steering Committee (SSC), which I chair.

I will start my comment on NIOSH's new policy document for adding non-cancers by observing that no condition that is not a cancer has been added for over a decade.

From my reading, the new policy document continues a restriction from the old policy on the kind of scientific evidence that can be considered for the inclusion of non-cancers. Only epidemiological studies of the 9/11 population itself are to be evaluated by the Science Team, while studies of comparison populations exposed to one or more known 9/11 agents would be excluded, as would be other kinds of studies, however careful and well-validated. Nor would studies of any kind be considered, unless produced by an agency of the US government.

Of further concern to us is that the consequences of these restrictions would fall very unequally on the several populations meant to be served by the Zadroga Act. Direct epidemiological studies are more feasible in responders – where large cohorts were created relatively early following the disaster, and where eligibility was based on exposures during response activities. These groups are overwhelmingly male and were adults on 9/11 -- in contrast with the more diverse survivor population that includes women and children, who can develop different conditions that will not be captured by these WTCHP studies.

Under the Zadroga Act, adding a new condition depends on the weight of research evidence that supports a link between exposures to 9/11 agents and that condition.

Under the new policy, as with the old policy, however, adding a new condition depends on the weight of the research evidence defined as '*available'* to the Science Team, and on the Team's interpretation of that evidence.

The role of the Science Team is crucial to determining whether there is potential merit in any petition to add a new condition – whether that petition can move forward. And, again, the policy document directs the Science Team to consider only epidemiological studies of the 9/11 population itself that are *also* studies issued by a US government agency.

The policy document distinguishes among different degrees of evidence. Because we are unlikely to see overwhelming evidence of disease causation in the form of epidemiological studies of the 9/11 population any time soon, I will move past the 'Substantial Likelihood' category to the 'High Likelihood Category,' the only other category under which there is potential for a condition to be added. Again, it is the Science Team that reports back to the Administrator on the weight of the *available* research evidence for adding that condition. And that would be the evidence (and the

evaluation of evidence) that the Administrator weighs in deciding whether to add the condition outright or to engage the STAC – or, presumably, to take no action.

So the question is: How does this policy pose a potential obstacle to adding a condition? (And here I will apply some lessons learned from the Uterine Cancer deliberation that I think are relevant to the non-cancers policy document.)

The new policy does this in at least 3 ways. And in fact, the Rule acknowledges these 3 limitations or biases in the 'available' evidence, and in the Science Team's White Paper. They are:

1) **The overreliance on epidemiological studies of 9/11 exposed populations** that the policy appears to privilege and that shaped the Science Team's Uterine Cancer White Paper. Epidemiological evidence will come too late for many survivors and responders, who will struggle on their own to find *and to afford* proper diagnoses and treatment from doctors outside the Program

   Fortunately, another kind of evidence was put forward, and the addition of uterine cancer was based not on epidemiological studies but on mechanistic studies of Endocrine Disrupting Chemicals (EDCs)The scientific rationale provided by the Medical Directors of the Centers of Excellence was decisive (based on the role of EDCs in causing uterine cancer). Without this extraordinary effort, however, would any uterine cancer petition, or submission have succeeded?

2) **The overreliance on government studies and databases, some of which are outdated.**

   ~~T~~he summary of the Peer Review cited in the Rule adding Uterine Cancer zeroed in on this problem:

   *"The reviewer found the assertion in the 2021 White Paper that "[n]one of the 9/11 Agents identified as EDCs have been found by NTP, IARC, or EPA to be known to cause or be reasonably anticipated to cause uterine cancer" to be misleading because (1) the exposures studied by these organizations may not be comparable to the extensive exposures experienced by WTC responders and survivors; (2) the reviews conducted by NTP, IARC, and EPA are often outdated;"**

   Going forward, the Science Team should not rely solely on government studies but should conduct an expanded search of published/peer-reviewed studies as cataloged in the National Library of Medicine's searchable PubMed database.

*I also want to note the Science Team's decision, in response to a Peer Reviewer's comments, to remove the EPA's carcinogenicity classification column from its final White Paper.*The Science Team also has acknowledged Reviewer B's concerns that the EPA classifications of carcinogenicity are not always up to date and should not be relied upon for current scientific knowledge. Some EPA evaluations of the carcinogenicity of 9/11 agents in the Inventory were conducted decades ago […] To address these concerns, the Science Team has decided to remove the EPA carcinogenicity classification column from Table 3 of the final White Paper.*

We suggest that appropriate subject matter experts be engaged to work with the Science Team to ensure a more complete evaluation of the evidence. The 9/11 community deserves a consideration of state of the art research both within and beyond the WTCHP research portfolio.

3) **The overreliance on occupational cohorts, including 9/11 responder cohorts, that are overwhelmingly male.**

I quote again from the Rule adding Uterine Cancer:

"Reviewer C indicated that "women's health and women's health related cancers have been under examined and grossly understudied,"

STAC survivor representative Mariama James made this point about the most heavily researched WTC cohorts during the STAC's 2021 Uterine Cancer deliberation when she said, "you cannot know how 9/11 exposures are impacting women and children by studying only 50-year old men."

9/11-affected women and people exposed as children remain grossly understudied. Physical health impacts to children, the most vulnerable to harm from environmental toxins, constitute the largest and most persistent WTC knowledge gap. The SSC has long pushed for the WTCHP to create a representative cohort of people exposed as children. Because this cohort would be 50% female, and followed longitudinally, it would track the emergence of 9/11-related women's health problems, as well as conditions that are not unique to women.

Now that this new cohort has been authorized by the 117th Congress, the SSC is asking the Administrator to convene the STAC for a public meeting to discuss the Program's ideas and plans for creation of the new WTC cohort. Subject matter experts should be engaged as presenters, including Dr. Joan Reibman, Survivor Program Medical Director. We would also suggest including experts who have formed or worked with longitudinal cohorts of environmentally exposed individuals.

In addition, survivor stakeholders, including survivors exposed to the disaster as children, must play a major and meaningful role in shaping cohort-related plans prior to any implementation. In order to succeed, this effort will need robust ongoing survivor engagement.

The new cohort is a critical and major undertaking that we believe can fill longstanding knowledge gaps, and in doing so correct research inequities, and potential care inequities that result. The creation of the cohort needs and deserves a STAC meeting as the space for a focused public dialogue between experts, stakeholders and the Program.

Thank you for this opportunity to comment.