

STAC Recommendations on Independent Peer Review and the Policies and Procedures used to Add Conditions to the List of Covered Conditions

Recommendation 1.

The peer review and public comment should be sequential so the public commenters have access to the peer review comments.

Recommendation 2.

For any condition for which the Administrator determines there is modest or substantial support for adding it as a WTC covered condition the Administrator should secure external peer review of the determination.

Recommendation 3.

Any written peer reviews should be made public whether or not the Administrator determines to propose rulemaking.

Recommendation 4.

To the extent feasible, the Administrator and peer reviewers should consider scientific evidence beyond 9/11 studies including epidemiologic, toxicologic, and mechanistic studies when relevant.

Recommendation 5.

The Administrator should develop and implement a process to solicit from the public recommendations of scientific experts to perform peer review.

Recommendation 6.

A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a peer review is required. This could be done by an open solicitation by which persons could be nominated, a process that could be repeated periodically. Peer reviewers should be individuals with background and experience in relevant occupational and environment research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to WTC health effects and hazards, disasters, and other relevant exposures. In forming this pool, we advise that no exclusionary criteria be applied. Other persons could be chosen as peer reviewers based on their expertise if appropriate peer reviewers are not found in the pool.

Recommendation 7.

NIOSH should develop a transparent, written COI policy for selection of peer reviewers, to ensure that bias can be minimized in the peer review process and the outcome of the review achieves maximum credibility. The identity of the peer reviewers and their areas of expertise should be made available to the public after the review is completed along with written review comments and the Program's responses with attribution of specific comments to specific reviewers.

Recommendation 8.

The WTC administrator should be responsible for ensuring that the peer review process and reviewers are balanced and expected to give an unbiased scientific review. The selection of the peer reviewers should be made by NIOSH with consideration of the subject matter relevant to the petition. The peer review pool may also be useful to NIOSH to identify consultants to assist NIOSH with their initial scientific review of the evidence supporting the addition of a condition. NIOSH may consider, if needed, the retention of an outside contractor (with specific guidelines developed by NIOSH) to select the peer reviewers and coordinate the review.

Recommendation 9.

NIOSH Science Team should seek input of expert consultants when needed in definition of a proposed WTC-related health condition including symptoms, clinical findings, imaging and laboratory findings.

Recommendation 10.

The NIOSH Science team, when evaluating a petition, should include experts with a range of relevant expertise, including, at a minimum, clinical medicine, epidemiology, exposure assessment (preferably including but not limited to WTC exposures), and industrial hygiene. These are the core disciplines that are needed to address elements of the specified policy and procedures for adding conditions to the list of WTC-related health conditions, including biological gradient, plausibility, coherence and exposure qualifications. If possible, NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH Science team in the review of additional proposed conditions, including psychiatry, cardiology, rheumatology, and others if needed.

Recommendation 11.

The program should consider whether the mechanism of a STAC teleconference or other mechanism could be used to solicit external comments when a petition is likely to advance to the WTCHP Science Team assessment phase. We see this as distinct from a formal request by the Administrator for the STAC to make a recommendation on a petition and as a mechanism to allow opportunity for public comment and benefit from the scientific expertise and knowledge base of the STAC.

Recommendation 12.

The Policy and Procedures for Non-Cancer Conditions describes three potential phases of the NIOSH Science team review of scientific evidence: 1) initial review (p. 2); 2) a fuller assessment (p. 3-4); and 3) if “modest support” is found, a supplemental assessment of additional scientific literature (p. 5). This supplemental assessment is limited to epidemiologic studies of 9/11 agents with special emphasis on the relevance of exposure conditions. It would be important to give the NIOSH Science team some flexibility in the range of scientific studies they review by adding at the end of Section IV.B.1.d.i. (p. 5, line 9) the phrase “and additional knowledge based on peer-reviewed scientific studies that they deem highly relevant.”