Procedures for Adding a Non-Cancer Health Condition to the List of WTC-Related Health Conditions

Initiation

Proposed Addition Initiated at Administrator's Discretion
*Section II.A**

OR

Administrator Receives Valid Petition and Initiates Petition Process
Section II.B

* Sections referenced in *italics* throughout refer to the WTC Health Program's "Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions."

Science Team Evaluation

Conducts literature review to identify peer-reviewed, published, epidemiologic studies of the health condition among 9/11-exposed populations
Section III.B

Evaluates the science quality of each study and summarizes high-quality studies
Section III.C & III.D

Applies Bradford Hill criteria and assesses the representativeness of the body of evidence
Section IV.A

Based on the totality of the scientific evidence, the Science Team assesses the degree to which the evidence supports a causal association between 9/11 exposures and the health condition and categorizes the evidence
Section V

Science Team Evaluation Outcomes

Category I
Evidence Supports Substantial Likelihood of Causal Association
Section V.A

Category II
Evidence Supports High Likelihood of Causal Association
Section V.B

Category III
Evidence Supports Limited Likelihood of Causal Association
Section V.C

Category IV
Evidence Does Not Support Causal Association
Section V.D

Category V
Evidence is Inadequate to Determine a Causal Association
Section V.E

Administrator *may* direct Science Team to conduct discretionary secondary evaluation of additional highly-relevant scientific information regarding non-9/11 exposures
Section V.B.1.B

Science Team advises Administrator of evaluation findings and categorization
Section VI

Administrator Review

Administrator *may* request recommendation from WTCHP STAC**
Section VII

Administrator reviews Science Team findings and STAC recommendation, if any, and determines whether there is sufficient evidence of a causal association to propose adding a health condition to the List
Section VIII

** The Administrator may engage the Scientific/Technical Advisory Committee (STAC) at any point in the process prior to the determination.

Administrator Determination

Sufficient Evidence of Causal Association
Section VIII.A

Insufficient Evidence of Causal Association
Section VIII.B

No Evidence of Causal Association
Section VIII.C

Outcomes

Publish a Notice of Proposed Rulemaking to Add Health Condition
Section X.A

Independent Peer Review and Public Comment
Section X.B and X.C

Publish a Final Rule To Add (or Not Add) the Health Condition
Section X.D

Publish a Notice of Insufficient Evidence
Section IX.B

Publish a Determination Not to Add a Health Condition
Section IX.C