### **WORLD TRADE CENTER**

## HEALTH PROGRAM



Shanksville



**New York City** 



Pentagon

Update on 'Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions'

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Tania Carreón-Valencia, PhD Associate Director for Science World Trade Center Health Program National Institute for Occupational Safety and Health



# P&P for Adding Non-Cancer Health Conditions Pathways to Add a Non-Cancer Health Condition to the List<sup>1</sup>

- 1. The Administrator of the WTC Health Program initiates the process at his own discretion; or
- 2. The Administrator initiates the process after receiving a valid petition<sup>2</sup> from an interested party

A health condition may only be added to the List by rulemaking



<sup>&</sup>lt;sup>1</sup>https://www.cdc.gov/wtc/pdfs/WTCHP PP Adding NonCancers 14 February 2017.pdf

<sup>&</sup>lt;sup>2</sup> Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions" May 14, 2014 http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf

# **P&P for Handling Submissions and Petitions Determining Validity of Submission as a Petition**

- Policy Coordinator evaluates submission to determine if the submission meets the <u>requirements for a valid petition</u>
- The medical basis may be demonstrated by:
  - Reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations
  - Clinical case reports of health conditions in WTC responders or survivors
  - First-hand accounts or anecdotal evidence may not be sufficient to establish medical basis
- The submitter is notified if submission is considered a valid petition or not



# P&P for Adding Non-Cancer Health Conditions Literature Review

- The Program Science Team leads a review of the scientific literature:
  - Systematic literature search of published, peer-reviewed epidemiologic studies of 9/11-exposed populations
  - Evaluation of Scientific Evidence:
    - Science quality limitations
      - confounding, recruitment bias, exposure assessment, blinding, comparison group, selective reporting, conflict of interest
    - Application of Bradford Hill Criteria
      - strength of the association, precision of risk estimate, consistency of association, biological gradient, plausibility and coherence
    - Representativeness evaluation
      - 9/11 responder and/or survivor populations

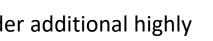


### **P&P** for Adding Non-Cancer Health Conditions Scientific Evidence Evaluation

### **Evidence supports causal association**

The Administrator will propose adding the health condition to the List

### Evidence supports high likelihood of causal association



 The Administrator may direct the Science Team to consider additional highly relevant scientific evidence from sources using non-9/11-exposed populations

### Limited or Inadequate Evidence of Causal Association

The Administrator will publish a Notice of Insufficient Evidence in the *Federal* Register

### Evidence does not support causal association

 The Administrator will publish a Notice of Determination Not to Propose a Rule to Add a Condition in the *Federal Register* 



# P&P for Adding Non-Cancer Health Conditions Scientific Evidence from Non-9/11-Exposed Populations

- Identification of scientific evidence
  - Additional peer-reviewed, scientific evidence obtained from an authoritative scientific source <u>published</u> by the U.S. government
- Review of scientific evidence
  - Provides a scientific basis for a determination
  - Fills an important gap in establishing a causal association
  - Mitigates the quality limitations found in studies of the health condition among 9/11-exposed populations
  - Evaluation of the similarity of exposure conditions to 9/11 exposure conditions
  - Review of source limitations



# P&P for Adding Non-Cancer Health Conditions Administrator's actions

### A. Request a recommendation of the STAC -

 If the expertise of the STAC would be helpful in making a determination on whether to propose the addition of a health condition to the List

### B. Publish a Notice of Proposed Rulemaking to Add the Health Condition

 If the evidence supports that it is substantially likely that the health condition is causally associated with 9/11 exposures

# C. Publish a Notice of Determination Not to Propose a Rule to Add a Condition

 If the evidence supports that the health condition is not causally associated with 9/11 exposures

#### D. Publish a Notice of Insufficient Evidence

If the evidence is insufficient to take either of the actions in B or C



# P&P for Adding Non-Cancer Health Conditions STAC recommendation on whether to add a new health condition to the List

- If the Administrator chooses to seek a STAC recommendation, he must make his request to the STAC within 90 days of receipt of the petition
  - A letter is sent to STAC Chair requesting that the STAC provide a recommendation including the scientific and medical basis for the recommendation
  - The STAC will submit its recommendation within 90 days or by a date specified by the Administrator (not to exceed 180 days)
- After receiving the STAC recommendation, the Administrator evaluates the recommendation and, within 90 days, publishes an NPRM proposing to add the condition or a notice of a determination not to propose a rule



# P&P for Adding Non-Cancer Health Conditions Rulemaking to Add a Health Condition

- A. Notice of Proposed Rulemaking
  - Proposed addition is published in the Federal Register
- B. Independent peer-review ->
- C. Public comments
- D. Final Rule



# P&P for Adding Non-Cancer Health Conditions Independent Peer Review

### 1. Selection of Peer Reviewers

- The Administrator will periodically develop a pool of potential peer reviewers by requesting recommendations from the STAC and a solicitation published in the *Federal Register*
- When a health condition is being proposed for addition to the List, the Administrator will select three subject matter experts to perform a peer-review
  - The Administrator will give initial consideration to the pool; if he cannot select from the pool, he will select at his discretion
  - Will balance medical and/or scientific expertise, independence from NIOSH and CDC, and previous service as peer-reviewer.



# P&P for Adding Non-Cancer Health Conditions Independent Peer Review

- 1. Selection of Peer Reviewers (cont.)
  - The Administrator will apply <u>Federal science agency conflict or bias</u> <u>prevention methods</u> to:
    - Limit potential conflicts of interest
    - Ensure that bias is minimized
    - Achieve a high level of credibility
    - Balance extremes in scientific perspectives



# P&P for Adding Non-Cancer Health Conditions Independent Peer Review

### 2. Charge to Peer Reviewers

- Peer reviewers will be asked to review the assessment of the evidence
- They will provide a written report answering the following questions:
  - 1. Are you aware of any other studies which should be considered?
  - 2. Have the requirements of the Policy and Procedures been fulfilled?
  - 3. Is the interpretation of the available evidence appropriate and does it support the conclusion to add the health condition, as described in the regulatory text, to the List?
- Report is due within 30 days of NPRM publication
- Peer reviews will be compiled and posted to the NIOSH rulemaking docket
- Peer reviewers will be identified without individual attribution of their comments



# **P&P for Adding Non-Cancer Health Conditions**Rulemaking to Add a Health Condition

- A. Notice of Proposed Rulemaking
- B. Independent peer-review
- C. Public comments
  - Public comment period will remain open 45 days after publication of NPRM to allow an additional 15 days to comment after peer reviewers' comments are posted

### D. Final Rule

- Public comments and peer reviews will be considered and responded to in the final rule preamble
- Administrator determines whether evidence continues to support addition of health condition to the List and, if so, publishes a Final Rule
- Following publication, the WTCHP will develop implementation procedures