



Shanksville



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Pentagon

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

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P&P for Adding Non-Cancer Health Conditions

Pathways to Add a Non-Cancer Health Condition to the List¹

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 petition² from an interested party

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

¹https://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_14_February_2017.pdf

² 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 requirements for a valid petition
- 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

1. **Evidence supports causal association**
 - The Administrator will propose adding the health condition to the List
2. **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
3. **Limited or Inadequate Evidence of Causal Association**
 - The Administrator will publish a Notice of Insufficient Evidence in the *Federal Register*
4. **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 published 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**

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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.

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Independent Peer Review

1. Selection of Peer Reviewers (cont.)

- The Administrator will apply Federal science agency conflict or bias prevention methods to:
 - Limit potential conflicts of interest
 - Ensure that bias is minimized
 - Achieve a high level of credibility
 - Balance extremes in scientific perspectives

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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