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## Overview of Policy and Procedures to Add Non-Cancer Conditions

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## Pathways To Add A Non-Cancer Health Condition To The List:

[http://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_Adding\\_NonCancer\\_Conditions\\_Revision\\_11\\_May\\_2016.pdf](http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf)

1. The Administrator of the WTC Health Program initiates the process at his own discretion;
  2. The Administrator initiates the process after receiving a petition by an interested party.
    - “Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions” (<http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf>) and determines whether the submission meets the requirements for a petition specified in 42 C.F.R. § 88.17(a)(1).
- A health condition may only be added to the List by rulemaking.

## P&P Non-Cancer – Literature Review

- The Program Science Team leads a review of the scientific literature:
  - Systematic Literature Search.
  - Literature Evidence Review:
    - Peer-reviewed, published, epidemiologic studies of 9/11-exposed populations.
    - Quantity and quality of the evidence.
    - If process was initiated in response to a petition, the medical basis is also reviewed.
- Findings of the review are documented and discussed with the Administrator.

## P&P Non-Cancer – Administrator Determination

1. If the evidence does not provide a sufficient basis for a decision:
  - Evaluation is documented and archived.
  - If initiated by a petition, determination published in the *Federal Register* and petitioner is notified in writing.
  
2. If the available evidence has the potential to provide a basis for a decision, the Administrator may:
  - Direct the Science Team to assess the scientific and medical evidence.
  - Request advice from the STAC.

## P&P Non-Cancer – Assessment of Information

- Science Team conducts an assessment of peer-reviewed, published, epidemiologic studies of 9/11-exposed populations by applying criteria extrapolated from the Bradford Hill criteria:
  - Strength of the association between a 9/11 exposure and the health condition, including the precision of the risk estimate.
  - Consistency of the findings across multiple studies.
  - Biological gradient, or dose-response relationships between 9/11 exposures and the health condition.
  - Plausibility and coherence with known facts about the biology of the health condition.

## P&P Non-Cancer – Administrator Actions for Substantial Support

- If the evidence provides substantial support for a causal association between 9/11 exposures and the health condition, then the Administrator publishes in the *Federal Register* a notice of proposed rulemaking to add the health condition to the List of WTC-Related Health Conditions.
- If the evidence provides substantial support against a causal association between 9/11 exposures and the health condition, then the Administrator publishes in the *Federal Register* a determination not to propose a rule and the basis for such determination.
- If the evidence is insufficient to provide substantial support for or against a causal association between 9/11 exposures and the health condition, then the Administrator publishes in the Federal Register a determination that there is insufficient evidence to add the health condition to the List at this time.
  - Note: This assessment of information for non-cancer health condition parallels Method 1 of the P&P Cancer.

## P&P Non-Cancer – Administrator Actions For Modest Support

- If evidence provides only modest support for a causal association between 9/11 exposures and the health condition, the Administrator requests additional assessment of whether a causal association is supported by other published, peer-reviewed, epidemiologic studies of associations between 9/11 agents and the health condition.
  - Other studies must include an assessment of the similarity of the exposure conditions to 9/11 terrorist attacks and cleanup (i.e., magnitude, route of exposure, physical form, duration, timing).
  - For outcomes from sub-chronic exposures, the consistency of the presence of the 9/11 agent during the response and recovery should be assessed.
- Note: This assessment of information for non-cancer health conditions is similar to Method 3 of the P&P Cancer.

## P&P Non-Cancer – Administrator Actions For Modest Support II

- If the additional assessment enables substantial support for a causal association between 9/11 exposures and the health condition, then the Administrator publishes in the *Federal Register* a notice of proposed rulemaking to add the health condition to the List of WTC-Related Health Conditions.
- If the additional assessment cannot substantially support a causal association between 9/11 exposures and the health condition, then the Administrator publishes in the *Federal Register* that the evidence was insufficient to take action.



## P&P Non-Cancer – Assessment of Information – Other Methods

- Note 1: The WTC Health Program may provide treatment for a requested health condition found to be causally associated with a health condition on the List of WTC-Related Health Conditions if the requested health condition meets the WTC Health Program's definition of a medically associated health condition.
- Note 2: The Administrator's assessment of information for non-cancer health conditions may involve review of recommendations provided by the STAC, where the Administrator has requested such input.

## If Administrator Asks for STAC Advice - Timing

- If the Administrator decides to request a STAC recommendation for a petition, the Administrator must make the request within 90 days of receipt of the petition (to add a new health condition).
- If the Administrator requests a STAC recommendation (either following a petition or at the Administrator's discretion), a letter is sent to STAC Chair requesting advice and establishing a time period of 90 days (up to 180 days) for the committee to provide recommendations and the scientific and medical basis for those recommendations.
- After receiving the recommendations from the STAC, the Administrator evaluates and takes appropriate action no later than 90 days after receipt of the recommendation.

## P&P Non-Cancer – Rulemaking to Add a Health Condition

- **NPRM**
  - Proposed addition is published in the Federal Register.
  - Public Comments are solicited.
  - Peer reviewers are identified with consideration of STAC’s input to conduct an independent peer review.
- **Final Rule**
  - WTC Health Program considers and responds to comments by peer reviewers and the public.
  - Administrator determines whether evidence continues to support addition of health condition to the List of WTC-Related Health Conditions.