



Shanksville



New York City



Pentagon

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

Updated: May 1, 2019

Updated: September 11, 2019

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National Institute for Occupational Safety and Health

WTC-Related Health Conditions¹

- “[A]n illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition...;” or
- “[A] mental health condition for which such attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition....”

¹ See 42 U.S.C. § 300-22(a)(1); 42 C.F.R. § 88.1

Covered Condition Categories

1. Aerodigestive disorders
2. Mental health conditions
3. Musculoskeletal disorders (only for WTC responders to the New York City disaster area)
4. Cancers
5. Acute traumatic injuries

Conditions may be added to the list of covered conditions

List of WTC-Related Health Conditions (List) - See 42 C.F.R § 88.15

- Aerodigestive Disorders:

- Interstitial lung diseases
- Chronic respiratory disorder
- Asthma
- Reactive airways dysfunction syndrome (RADS)
- WTC-exacerbated and new onset COPD
- Chronic cough syndrome
- Upper airway hyperreactivity
- Chronic rhinosinusitis
- Chronic nasopharyngitis
- Chronic laryngitis
- Gastroesophageal reflux disorder (GERD)
- Sleep apnea associated with one of the above

- Musculoskeletal Disorders (Responders to NYC disaster area only)

- Mental Health Conditions:

- Post-traumatic stress disorder (PTSD)
- Major depressive disorder
- Panic disorder
- Generalized anxiety disorder
- Anxiety disorder
- Depression
- Acute stress disorder
- Dysthymic disorder
- Adjustment disorder
- Substance abuse

- Acute Traumatic Injuries

- Cancers (24 specific categories)

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

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 petition¹ from an interested party.

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

¹ 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>

Petition Form

Form Approved
OMB No. 0920-0929
Exp. Date 04/30/2015

Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

General Instructions

Any interested party may petition the WTC Program Administrator to add a condition to the List of WTC-Related Health Conditions (List) in 42 C.F.R. Part 88 (see <http://www.cdc.gov/wtc/faq.html#hlthcond> for the complete list).

Please use this form to petition the Administrator to add a health condition (any recognized medical condition requiring treatment or medication) to the List. Please use a separate form for each health condition.

Use of this petition *form* is voluntary, but any petition must include all of the information identified below, as required by 42 C.F.R. Part 88. Petitions that do not provide the required information will not be considered by the WTC Program Administrator. Additional supporting materials may be submitted and are encouraged.

Please note, however, the petition and all supporting materials submitted to the WTC Health Program are part of the public record and may be subject to public disclosure. Personal information will be redacted prior to public disclosure.

Please TYPE or PRINT all information clearly on the form.

If you need more space to provide the required information, please attach additional pages to this form.

Mail or email this form to: World Trade Center Health Program
395 E. Street, S.W., Suite 9200
Washington, D.C. 20201
WTC@cdc.gov

A. Interested Party Information

A1. Do you represent an organization (are you submitting this petition on behalf of an organization)?
 Yes (Go to A2) No (Go to A3)

A2. Organization Information:

Name of organization _____

A3. Name of Individual Petitioner or Organization Representative:

First name _____

Last name _____

Position, if representative of organization _____

A4. Mailing Address:

Street _____

City _____

State _____

Zip code _____

A5. Telephone Number: _____

A6. Email Address: _____

B. Proposed WTC-Related Health Condition Information

B1. Health Condition Information:

Name of health condition you wish to petition to add to the List of covered conditions _____

If the name of the condition is not known, please provide a description of the condition or the name of the diagnosis provided by a physician or other healthcare provider.



Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions

John Howard, M.D., Administrator
World Trade Center Health Program

May 14, 2014

I. Receipt and Routing of Submissions

Submissions requesting the addition of a health condition to the List of WTC-Related Health Conditions (List) will be date-stamped by the Office of the Administrator upon receipt and then routed to the World Trade Center (WTC) Health Program Policy Coordinator or designee.

II. Determining Validity of Submission as a Petition

A. Policy Coordinator's Initial Assessment

The Policy Coordinator will evaluate the submission to determine if the submission meets the requirements for a valid petition.

B. Requirements of a Valid Petition

<https://www.cdc.gov/wtc/pdfs/policies/WTCHPPPPetitionHandlingProcedures14May2014-508.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; or
 - 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.

Valid Petitions Received to Date - <https://www.cdc.gov/wtc/received.html>

001	Cancer	013	Autoimmune – Multiple Sclerosis
002	Prostate Cancer	014	Autoimmune – Rheumatoid Arthritis
003	Kidney Disease	015	Neuropathy
004	Cardiovascular Disease	016	Parkinson’s Disease & Parkinsonism
005	Acoustic Neuroma	017	Parkinson’s Disease & Parkinsonism
006	Primary Biliary Cirrhosis	018	Hypertension
007	Autoimmune Disease – Rheumatoid Arthritis	019	Irritable Bowel Disease
008	Autoimmune – Encephalitis of the Brain	020	Stroke
009	Autoimmune – Multiple Sclerosis	021	Deep Vein Thrombosis & Pulmonary Embolism
010	Peripheral Neuropathy	022	Monoclonal Gammopathy of Unknown Significance (MGUS)
011	Autoimmune – Lupus & Rheumatoid Arthritis	023	Endometrial Cancer
012	Atherosclerosis		



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

**John Howard, M.D., Administrator
World Trade Center Health Program**

March 21, 2014
Revised: May 14, 2014
Revised: October 21, 2014
Revised: May 11, 2016
Revised: February 14, 2017
Updated: May 1, 2019
Updated: September 11, 2019

Note for May 1, 2019 Update: This version incorporates non-substantive changes to update the definition of “9/11 agents” and describe the Inventory of 9/11 agents as established in the “Development of the Inventory of 9/11 Agents,” published July 17, 2018.

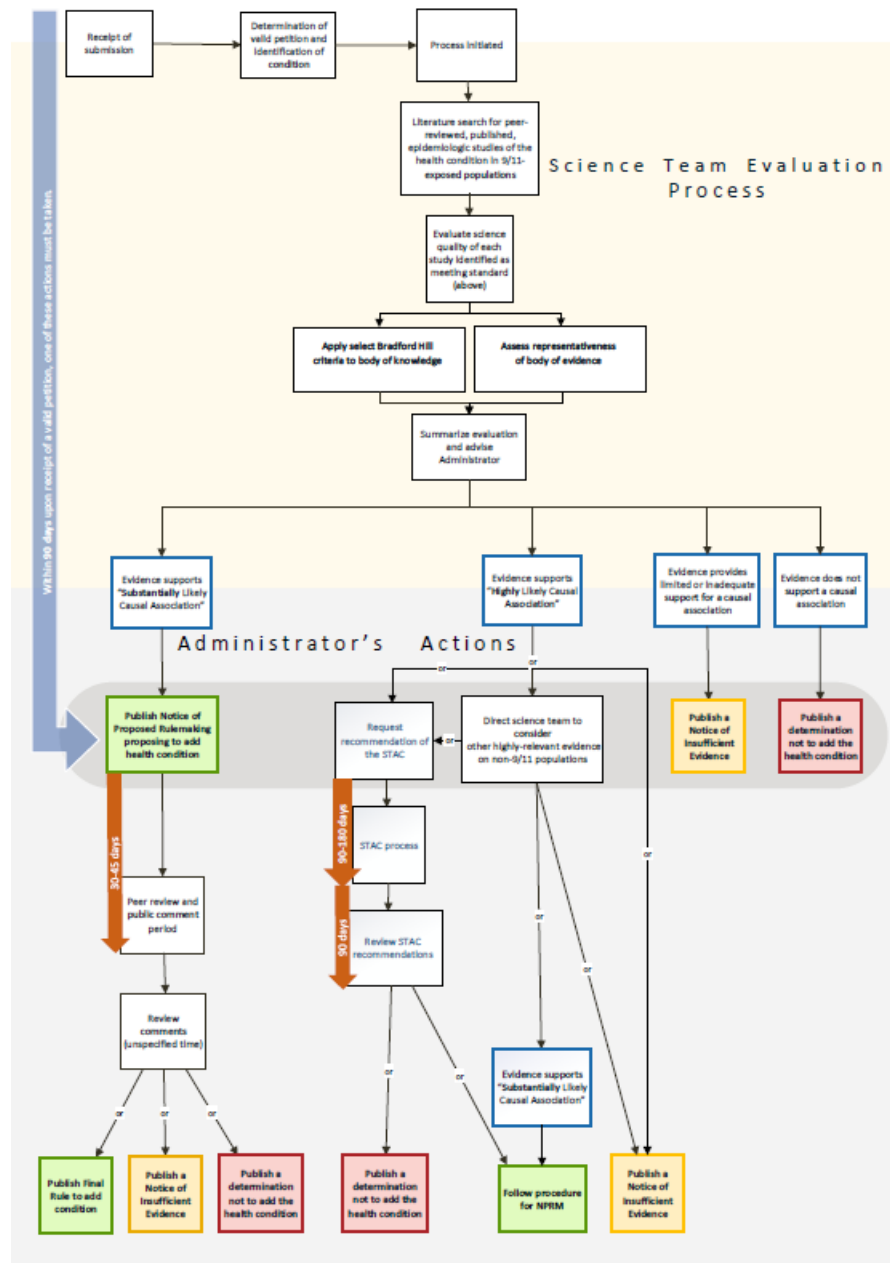
Note for July 8, 2019 Update: This version incorporates non-substantive changes to describe the process by which the Science Team evaluates the quality of scientific evidence, adds descriptions of the select Bradford Hill criteria used by the Science Team to evaluate causality, and provides an additional bibliographic reference.

I. Authority

The *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (“Act”)¹ and the World Trade Center (WTC) Health Program regulations.²

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


This flow chart applies only to situations where the Administrator receives a submission



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~~ evaluation**
 - confounding, recruitment bias, exposure assessment, blinding, comparison group, selective reporting, conflict of interest
 - **Application of Bradford Hill Criteria¹**
 - 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;
 - Request a recommendation from the STAC; or
 - Publish a Notice of Insufficient Evidence in the *Federal Register*.
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 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;
 - Request a recommendation from the STAC; or
 - Publish a Notice of Insufficient Evidence in the *Federal Register*.


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 Rulemaking to Add a Health Condition

- A. **Notice of Proposed Rulemaking (NPRM)**
 - 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

- At least every two (2) years, the Administrator will 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 (3) 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.
 - The Administrator 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 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; and
 - Balance extremes in scientific perspectives.

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

2. Charge to Peer Reviewers

- Review the assessment of the evidence
- Provide a written report within 30 days 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?*
- The Program will compile and post the reviews 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

- Administrator considers public's and peer reviewers' comments
- Administrator determines whether evidence continues to support addition of health condition to the List
 - If yes, publishes a Final Rule (comments are responded to in the preamble of the Final Rule) and develop implementation criteria (e.g. certification requirements)
 - If no, publish a Notice of Insufficient Evidence or a 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 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;
 - Request a recommendation from the STAC; or
 - Publish a Notice of Insufficient Evidence in the *Federal Register*.
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

2. Evidence supports high likelihood of causal association


- The Administrator may direct the Science Team to evaluate additional scientific evidence regarding exposures to known **9/11 agents**¹ in additional sources using non-9/11-exposed populations.
- 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 C.F.R. § 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites.

¹World Trade Center Health Program. Development of the Inventory of 9/11 Agents. July 17, 2018. Available at: https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf

P&P for Adding Non-Cancer Health Conditions Scientific Evidence from Non-9/11-Exposed Populations (cont.)

- **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**
 - Does the evidence:
 - Provide a scientific basis for a determination;
 - Fill an important gap in establishing a causal association;
 - Mitigate 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 Insufficient Evidence**
- If the evidence is insufficient to add the health condition to the List

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, must:
 - Publish an NPRM proposing to add the health condition to the List; or
 - Publish a notice of a determination not to propose a rule.

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;
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 - Publish a Notice of Insufficient Evidence in the *Federal Register*.
3. **Limited or Inadequate Evidence of Causal Association**
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P&P for Adding Non-Cancer Health Conditions Scientific Evidence Evaluation

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QUESTIONS?

DISCUSSION