



# World Trade Center Health Program

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

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**Note for January 22, 2026, Revision:** This version defines important terms and clarifies the following: (1) the scope of the policy and procedures; (2) the requirements of a petition; (3) how the medical basis requirement for a petition may be met; and (4) what types of scientific sources can and cannot be used to meet the medical basis requirement to be considered a petition.

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## I. Authority

The authority for the Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of World Trade Center (WTC)-Related Health Conditions (Policy and Procedures) is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (Act)<sup>1</sup> and the WTC Health Program (Program) regulations.<sup>2</sup>

The Act permits an interested party to petition the Administrator of the WTC Health Program (Administrator) to add a health condition to the List of WTC-Related Health Conditions (List).<sup>3</sup> The Administrator outlined the process by which an interested party may submit a request to add a health condition to the List in the WTC Health Program regulations implementing the Act.<sup>4</sup>

## II. Definitions

**9/11 agents** mean chemical, physical, biological, or other agents or 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. Known 9/11 agents are established in the WTC Health Program's Development of the Inventory of 9/11 Agents (*Inventory of 9/11 Agents*).<sup>5</sup>

**9/11-exposed population** means, for the purposes of this Policy and Procedures, those persons who can be reasonably assumed to have been exposed to hazards resulting from the September 11, 2001, terrorist attacks, including those 9/11 agents identified in the Program's Inventory of 9/11 Agents, within the geographic areas identified in the WTC Health Program's eligibility criteria; such populations may include, but are not limited to, WTC Health Program members.

**Hazard** means a chemical, physical, or biological agent or experience that may cause psychological harm. For the purposes of the WTC Health Program, hazards include, but are not limited to, the 9/11 agents identified in the Program's *Inventory of 9/11 Agents*.<sup>6</sup>

**Interested party** means a representative of any organization representing WTC responders, a nationally recognized medical association, a WTC Health Program Clinical Center of Excellence (CCE) or Data Center, a State or political subdivision, or any other interested person.<sup>7</sup>

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<sup>1</sup> Pub. L. 111-347, as amended by Pub. L. 114-113, Pub. L. 115-59, Pub. L. 117-328, and Pub. L. 118-31, Title I codified at 42 U.S.C. §§ 300mm-300mm-64.

<sup>2</sup> 42 C.F.R. Part 88.

<sup>3</sup> Zadroga Act, Sec. 3312(a)(6)(B), 42 U.S.C. § 300mm-22(a)(6)(B).

<sup>4</sup> See 42 C.F.R. § 88.16(a).

<sup>5</sup> See WTC Health Program, *Development of the Inventory of 9/11 Agents*, July 17, 2018,

[https://www.cdc.gov/wtc/pdfs/research/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://www.cdc.gov/wtc/pdfs/research/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf)

<sup>6</sup> See *supra* footnote 5.

<sup>7</sup> 42 C.F.R. § 88.1; see also 42 U.S.C. § 300mm-22(a)(6)(E).

**Inventory of 9/11 Agents** means those 9/11 agents identified in Tables 1–4 of the WTC Health Program’s publication, *Development of the Inventory of 9/11 Agents*.<sup>8</sup>

**In vitro study** means a study performed in a test tube, culture dish, or elsewhere outside a living organism.

**List of WTC-Related Health Conditions (List)** means those health conditions eligible for coverage by the WTC Health Program as identified in the Program regulations at 42 C.F.R. § 88.15.

**Medical basis** means a medical science explanation for adding a requested health condition to the List as described in Section VI.D.<sup>9</sup>

**Petition** means a submission that is determined to meet each of the requirements of a petition (Section VI.) and is found to be within the scope of this *Policy and Procedures*.

**Positive association** means a relationship between exposure to the 9/11 agent or hazard and the subsequent occurrence of the requested health condition suggesting that the health condition is more frequently observed in individuals exposed to the 9/11 agent or hazard than those not exposed.

**Scientific source** includes, but is not limited to, the following types of publications:

1. A published, peer-reviewed epidemiological or exposure assessment study;
2. A published, peer-reviewed case report or case series;
3. A single reference cited in a published, peer-reviewed literature review, meta-analysis, or systematic review of other published, peer-reviewed epidemiological studies;
4. An authoritative publication by the U.S. government, such as (i) the Toxicological Profiles published by the Agency for Toxic Substances and Disease Registry (ATSDR); (ii) Monographs published by the National Toxicology Program (NTP); and (iii) Human Health Risk Assessments published by the Environmental Protection Agency; or
5. A scientific abstract, news article, press release, set of conference proceedings, or similar document, which refers to, or reports on, any of the sources mentioned in 1 through 4 immediately above.

**Submission** means a written or electronic request sent to the Administrator to add a health condition to the List.<sup>10</sup>

### **III. Purpose**

The purpose of this *Policy and Procedures* is to explain how the WTC Health Program handles requests to the Administrator to add new health conditions to the List. If the

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<sup>8</sup> See *supra* footnote 5.

<sup>9</sup> 42 C.F.R. § 88.16(a)(1)(iv).

<sup>10</sup> A request to add a health condition to the List is considered a submission until it is determined to meet all the requirements of this *Policy and Procedures*; submissions determined to meet the requirements are a petition and eligible for scientific evaluation.

submission meets the requirements described in this *Policy and Procedures*, it will be considered a petition and thereby eligible for scientific evaluation by the Program.

#### **IV. Scope and Limitations**

A submission consisting of any of the following is beyond the scope of this *Policy and Procedures* and will not be considered a petition eligible for scientific evaluation by the Program.

##### **A. Beyond the Administrative Scope of the Petition Process<sup>11</sup>**

1. Requests to add a health condition already included on the List;
2. Requests to certify a health condition for an individual Program member based on information specific to that individual member;<sup>12</sup>
3. Requests to authorize treatment for a health condition;<sup>13</sup>
4. Requests to add a health condition that resulted from the treatment or progression of a health condition already on the List (i.e., a medically-associated health condition), unless the scientific source provided as a medical basis demonstrates a positive association between 9/11 exposures and the requested health condition;<sup>14</sup>
5. Requests to certify a health condition as medically associated with a health condition on the List;<sup>15</sup>
6. Requests to change an existing or develop a new WTC Health Program policy;<sup>16</sup>
7. Requests to change an existing or promulgate a new regulation unrelated to adding a health condition to the List in 42 C.F.R. § 88.15; and
8. Requests to change the Zadroga Act.

##### **B. Insufficient Scientific Source**

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<sup>11</sup> The requests described in this section would not be substantively addressed through the addition of a health condition to the List.

<sup>12</sup> Requests related to an individual member's specific certification or treatment approval for a health condition already on the List of WTC-Related Health Conditions or a health condition medically associated with a certified WTC-related health condition should be directed to the member's CCE or Nationwide Provider Network (NPN) or National Program Administrator (NPA). See Chapter 3, Section 5 of the Program's Administrative Manual at [https://www.cdc.gov/wtc/ppm.html#certification\\_physician](https://www.cdc.gov/wtc/ppm.html#certification_physician)

<sup>13</sup> See *supra* footnote 11.

<sup>14</sup> A health condition that either results from treatment of a certified WTC-Related Health Condition or results from progression of a certified WTC-Related Health Condition may be eligible for certification and coverage by the WTC Health Program as a "health condition medically associated with a WTC-Related Health Condition," see 42 C.F.R. § 88.1; see also WTC Health Program, Health Conditions Medically-Associated with World Trade Center-Related Health Conditions, November 7, 2014, <https://www.cdc.gov/wtc/pdfs/policies/WTCHPMedicallyAssociatedHealthConditions7November2014-508.pdf>

<sup>15</sup> See *supra* footnote 11.

<sup>16</sup> Requests pertaining to Program policies and procedures (e.g., requests to change the minimum latency requirements for cancers in the existing *Policy and Procedures for Minimum Latency & Types or Categories of Cancer*) are not handled through the petition process and should be addressed in writing to the Administrator. Letters to the Administrator should be sent to the mailing address listed at: <https://www.cdc.gov/wtc/contact.html> or via email to: [WTC@cdc.gov](mailto:WTC@cdc.gov)

1. Requests to add a health condition citing only an animal study or an *in vitro* study conducted in microorganisms or cells in culture;
2. Requests to add a health condition citing only medical information specific to an individual, such as information based on personal observations and/or an individual's medical records, laboratory and imaging results, or letters from treating physicians;
3. Requests to add a health condition citing a published description or explanation of the health condition without a specific reference to 9/11 exposures, such as an overview of the health condition on health-related websites (e.g., Mayo Clinic, WebMD, or similar website);
4. Requests to add a health condition citing only a study of treatment, i.e., medical procedure or medication, for the requested health condition; and
5. Requests to add a health condition citing a scientific abstract, a news article, a press release, a set of conference proceedings, or other similar document that only includes preliminary findings from an unpublished scientific source.

### **C. Limitations on Requests for Previously Evaluated Health Conditions**

A new submission requesting the addition of a health condition for which the Administrator previously evaluated the scientific evidence and found it to be insufficient to propose adding the condition will not be a petition eligible for scientific evaluation unless the submission provides a new medical basis for adding the health condition.<sup>17</sup>

1. The new medical basis must include a scientific source not previously reviewed for the requested health condition. The scientific source must have been published on or after the date of the literature search included in the Administrator's most recent determination not to add the health condition.<sup>18</sup>
2. A new medical basis can include, but is not limited to, a different scientific method, a different 9/11 agent, a different study population, or a more recent analysis.

## **V. Submission Receipt**

Upon receipt, a submission requesting to add a health condition to the List will be date-stamped by the WTC Health Program. The date-stamped submission will then be evaluated by the Program to determine whether the submission meets the requirements of a petition (Section VI.D.) and is within the scope of this *Policy and Procedures*.

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<sup>17</sup> See 42 C.F.R. § 88.16(a)(5).

<sup>18</sup> The “on-or-after date” will be the date of the literature review search identified in the Federal Register notice presenting the results of the scientific evaluation associated with the previous petition.

## VI. Petition Requirements<sup>19</sup>

### A. Intent to Petition

A petition must include a statement of intent to petition the Administrator to add a health condition to the List. Use of the optional petition form on the WTC Health Program's website is considered a statement of intent to petition the Administrator.<sup>20</sup> However, interested parties are not required to use the form for a submission to meet the intent-to-petition requirement.

### B. Interested Party Information and Signature

A petition must include the name, contact information, and signature of the interested party requesting the addition of the health condition to the List.

### C. Name of Health Condition Requested for Addition

#### 1. Specific Health Condition

A petition must include the name of a specific health condition, or a description sufficient in detail for the WTC Health Program to identify the name of the health condition being requested.<sup>21</sup>

#### 2. Unclear Health Condition

If the specific name of the requested health condition is unclear, the Administrator will review the name of the condition in conjunction with relevant medical sources, including the information provided as the medical basis in the submission, to determine the health condition requested. The Administrator may limit the scope of the requested health condition to align with the health condition described in the medical basis in the submission.

If the Administrator is unable to identify the name of the requested health condition, the submission will not be considered a petition, and the submitter will be informed of the Administrator's determination.

#### 3. Broad Categories or Grouping of Health Conditions

- a. A submission requesting that a broad category or grouping of health conditions be added to the List, e.g., cardiovascular system diseases, autoimmune system diseases, endocrine system diseases, or other body system disease grouping, will not satisfy this petition requirement.
- b. If a submission requests a broad category or grouping of health conditions, and the medical basis does not indicate a specific health

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<sup>19</sup> 42 C.F.R. § 88.16(a) provides that: "(1) Each valid petition must include the following: (i) An explicit statement of an intent to petition the Administrator to add a health condition to the List of WTC-Related Health Conditions; (ii) Name, contact information, and signature of the interested party petitioning for the addition; (iii) Name and/or description of the condition(s) to be added; (iv) Reasons for adding the condition(s), including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition(s) to be added."

<sup>20</sup> The optional petition form is available at <https://www.cdc.gov/wtc/petitions.html>.

<sup>21</sup> A submission describing only symptoms (e.g., pain, nausea, headache) or signs (e.g., fever, swelling, rash) associated with a particular health condition, without specifying the name of a health condition, does not meet this requirement and will not be considered a petition eligible for scientific evaluation.

condition within the broad category or group of health conditions, the submission will not satisfy this petition requirement.

- c. If a submission requesting a broad category or grouping of health conditions provides one of the medical bases described in Section VI.D. for one or more of the health conditions included within the broad category or grouping of health conditions, the submission will be considered to meet the medical basis requirement for those specific health conditions.

#### **D. Medical Basis**

A petition request must include the reason(s) for adding the condition, including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition to be added.<sup>22,23</sup> The medical basis must be scientific in nature and must be met by providing or referencing one of the following:

1. At least one published, peer-reviewed, epidemiological study in a 9/11 exposed population demonstrating a positive association between 9/11 exposures and the occurrence of the requested health condition;
2. At least one published, peer-reviewed case report or case series in a 9/11 individual or a group of individuals demonstrating a positive association between 9/11 exposures and the occurrence of the requested health condition;
3. At least one *scientific source*, as described in Section II., demonstrating a positive association between exposure to a 9/11 agent and the occurrence of the requested health condition in any population; or
4. At least one *scientific source*, as described in Section II., demonstrating both: (i) a positive association between exposure to a hazard (other than a 9/11 agent) and the requested health condition; and (ii) information that the hazard was present in one of the geographic areas identified in the WTC Health Program's member eligibility criteria found in 42 C.F.R. §§ 88.4 and 88.8.<sup>24</sup>

### **VII. Notification and Processing**

#### **A. Submission Does Not Meet Petition Requirements**

If a submission does not meet the requirements of this *Policy and Procedures*, the Administrator will notify the interested party who filed the submission and explain in writing why the submission does not meet the requirements.

#### **B. Submission Meets Petition Requirements**

If the submission is determined to meet all requirements of this *Policy and Procedures*, the WTC Health Program will take the following steps:

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<sup>22</sup> 42 C.F.R. § 88.16(a)(1)(iv).

<sup>23</sup> A study reporting a positive association between a 9/11 exposure and the requested health condition only with an accompanying or intervening health condition resulting from treatment or progression of a health condition already on the List, without demonstrating a positive association between 9/11 exposure and the requested health condition itself (e.g., a study that discusses PTSD as an intermediary condition between the 9/11 exposure and the requested health condition) will not be considered to meet the medical basis requirement.

<sup>24</sup> Each requirement of Section VI.D. may be satisfied by reference to the same or different scientific sources.

1. Designate the petition with a unique ordinal number;
2. Notify the interested party/petitioner in writing that their submission is determined to be a petition and is being evaluated by the Administrator;<sup>25</sup>
3. Post the petition with appropriate redactions (to protect any personally identifiable information (PII) included in the petition) on the WTC Health Program website;<sup>26</sup> and
4. Provide a copy of the petition to the HHS Office of the General Counsel (OGC) for its records.

## **C. Administrative Processing**

### **1. Multiple Petitions for the Same Health Condition**

- a. When multiple petitions are received from one or more interested parties to add the same health condition to the List, the Administrator may group multiple petitions together for purposes of conducting a single scientific evaluation.<sup>27</sup> If a combined scientific evaluation is utilized, the Administrator will publish the results of the combined scientific evaluation in a single *Federal Register* notice or Notice of Proposed Rulemaking.
- b. If a petition<sup>28</sup> requires the evaluation of a health condition that was the subject of a prior scientific evaluation, a new evaluation may be added as an appendix to the existing scientific evaluation.

### **2. Multiple Requested Health Conditions in a Single Petition**

- a. When a single petition requests the addition of more than one health condition to the List and the petition provides sufficient medical basis for each requested health condition, the Administrator may choose to scientifically evaluate each requested health condition separately.
- b. The Administrator may choose either to publish a separate *Federal Register* notice for each requested health condition or may publish a single *Federal Register* notice or Notice of Proposed Rulemaking for the requested health conditions in the petition.

## **VIII. Petition Evaluation**

Following a determination that the submission meets the requirements of a petition, the WTC Health Program will conduct a scientific evaluation of the petition as

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<sup>25</sup> Petitions are evaluated by the Administrator in accordance with 42 U.S.C. § 300mm-22(a)(6) and 42 C.F.R. § 88.16.

<sup>26</sup> Petitions will be redacted in accordance with requirements of the Privacy Act (5 U.S.C. § 552a), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d), and associated implementing regulations. The WTC Health Program will post the redacted petition on its website at <https://www.cdc.gov/wtc/received.html>.

<sup>27</sup> See 42 C.F.R. § 88.16(a)(4).

<sup>28</sup> Each subsequent petition of a previously evaluated health condition must provide new medical basis. See Section IV.C.

described in the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*.<sup>29</sup>

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<sup>29</sup> For non-cancer conditions, the WTC Health Program will evaluate the requested health condition by following the WTC Health Program's *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* (October 18, 2024).

[https://www.cdc.gov/wtc/pdfs/policies/WTCHP\\_PP\\_Adding\\_NonCancer\\_Health\\_Conditions\\_20241018.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancer_Health_Conditions_20241018.pdf). For cancers, the WTC Health Program will evaluate the requested condition by following the WTC Health Program's *Policy and Procedures for Adding Types of Cancer Conditions to the List of WTC-Related Health Conditions* (November 18, 2011), [https://www.cdc.gov/wtc/pdfs/policies/WTCHP\\_PP\\_Adds\\_Cancer\\_11182011-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adds_Cancer_11182011-508.pdf)