

**National Institute for Occupational Safety and Health**

**World Trade Center Health Program Petition for the Addition of a  
New WTC-Related Health Condition for Coverage under the World  
Trade Center (WTC) Health Program 0920-0929**

**Mini-supporting statement**

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## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

#### **Background**

This is a mini-supporting statement to account for non-substantive changes to 0920-0929 (World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center Health Program, expiration 4/30/2015).

The James Zadroga 9/11 Health and Compensation Act of 2010 (the Act) established the World Trade Center (WTC) Health Program. The law requires the WTC Health Program to provide monitoring and treatment benefits to responders and survivors who are determined to be eligible for the Program. The Act included a list of WTC-related health conditions (42 CFR § 88.1) which are covered for treatment by the Program. The Act also allows any interested party to petition the WTC Program Administrator to add a condition to the list. The Program has created a form that has been approved by OMB (0920-0929) to help an individual(s) provide the necessary information to request the Program Administrator to add a condition.

The revised form improves clarity for the petitioner and to accurately reflect the current list of covered conditions. The following changes will be made:

- In the first sentence of the General Instructions section, the current petition refers people to page 5 for a full list of covered conditions. Since that list has changed over time we are going to remove that sentence and page 5 of the listed conditions and refer people to the website for the full and current list of covered conditions. This will prevent any future changes to the petition form as the current list is always updated on the website.
- The language was modified in section C1 to make it clearer what information needs to be provided by the petitioner in support of the petition.
- Minor grammatical changes have been made to throughout the form for clarity.

No additional burden will be added to the respondents as this collection is already accounted for in the current OMB package (0920-0929). The respondent does not complete any additional paperwork as the edits are minor changes to current language on the applications.

#### **Privacy Impact Assessment**

##### **Overview of the Data Collection System**

The data collection system involves the petitioner filling out a paper petition form or submitting a document containing the same data elements as requested by the petition

form. Those data elements include the interested party's name, contact information, signature, and a statement about the medical basis for the relationship/association between the 9/11 exposure and the proposed health condition, which will be used to make a determination about adding the health condition to the list of WTC-related health conditions. Once the petition is completed the petitioner will mail or email the completed petition to the WTC Health Program. The submission of a petition is purely voluntary, and is not required or otherwise compelled by NIOSH or the WTC Health Program.

### **Items of Information to be Collected**

The categories of Information in Identifiable Form (IIF) to be collected include:

- Name – First, Middle, and Last
- Organization
- Mailing Address – Address, City, State, Zip Code
- Phone Number
- Email Address
- Signature
- Medical basis for addition of the health condition (although not required by the Program, we anticipate that petitioners might include medical records to substantiate their petition)

### **Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age**

The NIOSH website (<http://www.cdc.gov/niosh/topics/wtc/>) has several pages devoted to the WTC Health Program. The petition form will be available for download from the webpage. This information is not directed at children under 13 years of age.

### **2. Purpose and Use of Information Collection**

This information is being collected to allow interested parties to request that the WTC Program Administrator consider the addition of a new health condition to the list of WTC-related health conditions in 42 CFR §88.1. The petitioner is required to provide the medical basis for proposing the condition, which the Administrator will use to determine whether to propose a rule to add the condition, to not to add the condition, or to seek a recommendation from the Scientific/Technical Advisory Committee (STAC).

### **Privacy Impact Assessment**

These data are being collected to allow interested parties to petition the WTC Health Program to add a health condition. The provided information will be used to assess the intent to petition the WTC Program Administrator and to determine the disposition of the petitioned-for health condition.

IIF will be collected from the petitions. While petitioners will not be asked to provide any IIF beyond the individual's name, signature, and contact information, NIOSH expects that some may submit medical records to substantiate a request to add a health condition. There will be a likely effect on the respondent's privacy if there were a breach of privacy. Access to data will be limited to authorized NIOSH project staff and the WTC Health Program STAC, whose members will review the medical information to determine whether the petitioned health condition should be added to the list of WTC-related health conditions in 42 CFR §88.1. All electronic data will be stored on secure servers accessible only with passwords.

### **3. Use of Improved Information Technology and Burden Reduction**

The petition process is not automated, although the applicant can download the petition form from the WTC Health Program website. Once the petitioner receives the form he/she must fill it out by hand. Once the petition is completed the petitioner can mail or email the completed form to the WTC Program Administrator.

### **4. Efforts to Identify Duplication and Use of Similar Information**

This is a new program and the data submitted by petitioners will be specific to health conditions potentially associated with exposures associated with the September 11, 2001, terrorist attacks. NIOSH expects each petition to contain novel information forming the medical basis for adding the proposed health condition; this information may not be available from any other source.

### **5. Impact on Small Businesses or Other Small Entities**

This data collection may affect small non-profit organizations that advocate on behalf of WTC responders and survivors. However, because this information collection is not mandatory, the burden on petitioner organizations is voluntarily incurred.

### **6. Consequences of Collecting the Information Less Frequently**

This data is submitted voluntarily by interested parties, and is not sought after, required or otherwise compelled by NIOSH or the WTC Health Program.

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice/Outside Consultation**

A. A 60-day notice was published in the *Federal Register* on July 1, 2011 (76 FR 38938, 38940) (see Attachment B). No public comments were received.

B. Because this is not a typical information collection, NIOSH did not consult with any persons outside the agency. However, NIOSH did consult with NIOSH and HHS colleagues familiar with the petition process associated with the Energy Employees Occupational Illness Compensation Program, and have developed the form and required data elements accordingly.

## **9. Explanation of any Payment/Gift to Respondents**

There will not be any payments made to or gifts given to respondents.

## **10. Assurance of Confidentiality Provided to Respondents**

IIF collected from petitions will be stored and maintained according to the HHS System of Records, 0920-0147, "Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH." NIOSH will release IIF to WTC Health Program STAC members, as necessary, in order for the STAC to make recommendations regarding the consideration of a new health condition for addition to the list of WTC-related health conditions.

### **IRB Approval**

This data collection is not research involving human subjects; IRB approval is not required.

### **Privacy Impact Assessment Information**

A. This submission has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable System of Records Notice is 0920-0147, Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH.

B. Access to data will be limited to authorized NIOSH project staff and WTC Health Program STAC members. All electronic data will be stored on secure servers accessible only with passwords. The un-redacted petitions, including Privacy Act-protected information, may be shared with the STAC since they are Special Government Employees who have received Privacy Act training. However, any discussion in a public meeting and any materials will be monitored and redacted appropriately. Anything the STAC considers becomes a STAC record subject to Privacy Act redactions. In addition, if a rule were to be promulgated regarding the addition of a condition, the initial petition

and all supporting documentation would be part of the rulemaking docket. Although the docket is usually un-redacted, in this situation we would follow the procedure of redacting such IIF as medical information.

C. On the petition form itself, petitioners are informed that information they submit is part of the public record and may be subject to public disclosure. Petitioners are also informed that IIF will be redacted prior to public disclosure.

D. Respondents are informed about the voluntary nature of their response. The petition form contains the following Privacy Act information:

### **Privacy Act Statement**

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. §552a), you are hereby notified of the following:

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. Sections 3311, 3312, and 3321 of Title XXXIII of the PHS Act require that the WTC Program Administrator develop regulations to implement portions of the WTC Health Program established within the Department of Health and Human Services (HHS). The WTC Health Program is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC). The information provided with this form and supporting documentation will be used by the WTC Program Administrator to consider the disposition of a petitioned-for health condition. Disclosure of this information is voluntary.

Records containing information in identifiable form become part of an existing NIOSH system of records under the Privacy Act, 0920-0147 "Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH." These records are treated in a confidential manner, unless otherwise compelled by law.

NIOSH may disclose information in identifiable form to the WTC Health Program STAC, which may be asked to consider the petition and issue a recommendation to the WTC Program Administrator. Information in identifiable form will be redacted from submitted petition forms and supporting documentation that become a part of the public record (e.g. in conjunction with STAC consideration or a rulemaking).

### **11. Justification for Sensitive Questions**

No sensitive questions are being asked of petitioners.

### **12. Estimates of Annualized Burden Hours**

HHS expects to receive no more than 100 submissions annually. We assume that interested parties will be enrolled WTC responders, screening-eligible survivors, certified-eligible survivors, or members of groups who advocate on behalf of responders or survivors, such as physicians. We estimate that an individual will spend an average of 40 hours gathering information to substantiate a request to add a health condition and assembling the petition.

**12A. Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Responder/ Survivor/ Advocate (physician)	Petition for the addition of health conditions	100	1	40	4,000

**12B. Estimated Annualized Burden Costs**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
FDNY Responder	1,000	\$24.08*	\$24,080
General Responder	1,000	\$18.20	\$18,200
Survivor	1,000	\$12.00	\$12,000
Physician advocate	1,000	\$91.10**	\$91,100
Total	4,000		\$145,380

\* Data from Bureau of Labor Statistics 2001 State Occupational Employment and Wage Estimates New York

\*\* Data from Bureau of Labor Statistics 2010 Healthcare Practitioners and Technical Occupations

**13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers**

There are no additional recordkeeping/capital costs.

**14. Annualized Cost to Federal Government**

Type of Federal employee support	Total Burden Hours	Hourly Wage Rate	Total Federal Costs
FTEs - Medical	100	\$100	\$10,000



<b>Type of Federal employee support</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Federal Costs</b>
and non-medical staff (review of petition sufficiency and consideration of medical basis)			
Special Government Employees - STAC members (consideration of medical basis)	612	\$40	\$24,480
Total			\$34,480

Our central assumption is that of the 100 submissions estimated to be received by the Program each year, only 3 will likely meet the criteria for a legitimate petition that will require Federal action. The total projected cost to the Government is \$34,480.

**15. Explanation for Program Changes or Adjustments**

This is a mini-supporting statement to account for the changes made to Attachment C.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Clearance is being requested for 3 years starting January 2012 and continuing through January 2015. The substance of petitions submitted to the WTC Health Program will be reported on the Program website, although protected IIF will be redacted. Petitions will be reported as they are processed.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

None.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

**B. Collection of Information Employing Statistical Methods**

Statistical methods will not be used to select respondents. Any interested party who

wishes to petition the WTC Program Administrator may do so.