

**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 (WTC) Health Program**

**Revision**

**Supporting Statement A**

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### B. Collection of Information Employing Statistical Methods

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#### Attachments

Attachment A	James Zadroga 9/11 Health and Compensation Act of 2010 (Title XXXIII Public Health Act §§3301 <i>et seq.</i> )
Attachment B	60-day Federal Register notice
Attachment C	Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program

- Goal of the study: This is not a study. PHS Act §3312(a)(3) identifies a list of health conditions for which individuals who are enrolled in the WTC Health Program may be monitored or treated. PHS Act §3312(a)(6)(B) specifies that interested parties may petition the Administrator of the WTC Health Program to request that a new health condition be added to the List of WTC-Related Health Conditions in 42 C.F.R. §88.1. To aid the petitioner, the WTC Health Program provides a petition form to be completed and then sent to the Administrator for review; the petitioner is not required to use the form, and may submit a petition in a different format, provided it contains all of the data elements requested on the form.
- Intended use of the resulting data: The WTC Health Program Administrator will use the information provided in each petition to determine whether to propose adding a new health condition for Program coverage.
- Methods to be used to collect: No statistical methods are used to collect this information.
- The subpopulation to be studied: This is not a study. Individuals who may submit petitions are individuals who responded to or survived the September 11, 2001 terrorist attacks.
- How data will be analyzed: No statistical methods are used to analyze the information collected. The Administrator will review each petition and determine whether to conduct a scientific analysis of the medical information presented.

## **A. Justification**

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

This is a request for a 3 year revision for OMB clearance from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors). PHS Act §3312(a)(3) identifies a list of health conditions for which individuals who are enrolled in the WTC Health Program may be monitored or treated. PHS Act §3312(a)(6)(B) specifies that interested parties may petition the Administrator of the WTC Health Program to request that a new health condition be added to the List of WTC-Related Health Conditions in 42 C.F.R. §88.1. To aid the petitioner, the WTC Health Program provides a petition form to be completed and then sent to the Administrator for review. However, the petitioner is not required to use the form, and may submit a petition in a different format, provided it contains all of the data elements requested on the form.

A revision is being requested in order to update the petition form. The petition form is amended slightly to reflect a WTC Health Program policy change. The current form asks respondents to offer reference to “a peer-reviewed, published, epidemiologic study.” The revised form will ask respondents to reference “peer-reviewed, published, epidemiologic and/or direct observational studies.”

## **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 C.F.R. §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).

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.

## **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**

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 January 22, 2015 (80 FR 3239). There were no public comments.

B. The WTC Health Program consulted with HHS OGC on the legal requirements needed for data collection.

**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 does not involve human subjects research; IRB approval is not required.

**Privacy Impact Assessment Information**

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.

- A. An overview of the data collection system: These data are being collected to allow interested parties to petition the WTC Health Program to add a health condition. The provided information is used to assess the intent to petition the WTC Program Administrator and to determine the disposition of the petitioned-for health condition.
- B. A description of the information to be collected: IIF is collected from the petitions. While petitioners are not asked to provide any IIF beyond the individual's name, signature, and contact information, some may submit medical records to substantiate a request to add a health condition. There would likely be an impact on the respondent's privacy if there were a breach of privacy. Access to data is limited to authorized NIOSH project staff and the WTC Health Program STAC, whose members may review the medical information to determine whether the petitioned health condition should be added to the List of WTC-Related Health Conditions in 42 C.F.R. §88.1. All electronic data is stored on secure servers accessible only with passwords.
- C. A description of how the information will be shared and for what purpose: Access to data is limited to authorized NIOSH project staff and WTC Health Program STAC members. All electronic data is 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 becomes part of the rulemaking docket. Although the docket is usually un-redacted, in this situation we follow the procedure of redacting such IIF as medical information.
- D. A statement detailing the impact the proposed collection will have on the respondent's privacy: 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.
- E. Whether individuals are informed that providing the information is voluntary or mandatory: 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).

- F. Opportunities to consent, if any, to sharing and submission of information: Because respondents are informed that their participation is voluntary, consent is given when the petition is submitted to the WTC Health Program.
- G. How the information will be secure: All information is secured in accordance with the Privacy Act.
- H. Whether a system of records is being created under the Privacy Act: As discussed above, 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.

**11. Justification for Sensitive Questions**

No sensitive questions are being asked of petitioners.

**12. Estimates of Annualized Burden Hours**

NIOSH expects to receive no more than 20 submissions annually. Petitioners include prospective and 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 spends 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	20	1	40	800

**12B. Estimated Annualized Burden Costs**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
FDNY Responder	200	\$24.08*	\$4,816
General Responder	200	\$18.20	\$3,640
Survivor	200	\$12.00	\$2,400
Physician advocate	200	\$91.10**	\$18,220
Total	800		\$29,076

\* 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 20 submissions estimated to be received by the Program each year, only 5 will likely meet the criteria for a legitimate petition that will require Federal action. Of those 5, only 1 or fewer are expected to be sent to the 17-member STAC for review. The total projected cost to the Government is \$34,480.

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

The total burden hours are changed from the original ICR because we overestimated the potential number of respondents; that number has been lowered due to WTC Health Program experience.

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

Clearance is being requested for 3 years starting in the summer of 2015 and continuing through 2018. 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.