

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**

**Request for Office of Management and Budget
Review and Approval for Federally Sponsored Data Collection**

January 17, 2012

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Attachments

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| 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 (76 FR 38938, 38940, July 1, 2011) |
| Attachment C | Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program |
| Attachment D | Draft Final Rule, World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions, 42 CFR §88.17 |

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a new Information Collection Request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), amending the Public Health Service Act (PHS Act), was promulgated on December 22, 2010, to establish the World Trade Center (WTC) Health Program to provide health examinations and treatment for emergency responders; recovery and cleanup workers; and residents, building occupants, and area workers who were directly impacted and adversely affected by the September 11, 2001, terrorist attacks. Attachment A contains the complete text of the Zadroga Act. Attachment B contains a copy of the 60-day *Federal Register* notice.

The Zadroga Act identified a list of health conditions for which individuals who are enrolled in the WTC Health Program may be monitored or treated [Title XXXIII, §3312(a)(3)]; those conditions are reiterated in the associated WTC Health Program regulations at 42 CFR §88.1. Under WTC Health Program regulations (42 CFR §88.17), interested parties may submit a petition to request that a new health condition be added to the list of conditions specified in 42 CFR §88.1.

To aid the petitioner, the WTC Health Program will provide a petition form to be completed and then sent to the Program 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 and identified below.

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)

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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 | Average Burden | Total Burden |
|---------------------------|------------------|---------------------------|----------------------|-----------------------|---------------------|
|---------------------------|------------------|---------------------------|----------------------|-----------------------|---------------------|

| | | | per Respondent | per Response (in hours) | 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 and non-medical staff (review of petition sufficiency and consideration of medical basis) | 100 | \$100 | \$10,000 |
| 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 new data collection.

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.