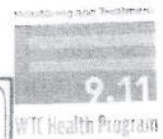
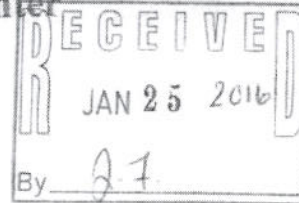


Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program

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

Public reporting burden of this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0929).

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:

Autoimmune Disease, Lupus and Rheumatoid Arthritis (RA)

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.

C. Basis for Proposing that the Condition Be Added to the List of WTC-Related Health Conditions

C1. Describe the reasons the WTC Program Administrator should consider the addition of this health condition. Explain how the health condition you are proposing relates to the exposures that may have occurred from the September 11, 2001, terrorist attacks. Your explanation must include a medical basis for the relationship/association between the 9/11 exposure and the proposed health condition. 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 to 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. If you need more space, please attach additional pages to this form.

See Attached Document

D. Signature of Petitioner

Sign your name below to indicate that you are petitioning the WTC Program Administrator to consider adding a health condition to the list of WTC-related health conditions identified in 42 C.F.R. Part 88.

Signature _____

1/23/16
Date

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, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH." These records are treated in a confidential manner, unless otherwise compelled by law.

Information submitted to WTC Health Program which may be considered "protected health information" pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191; 42 U.S.C. § 1320d) and the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164) will be maintained in accordance with all applicable laws.

NIOSH may disclose information in identifiable form only insofar as such disclosure is permitted pursuant to the HIPAA Privacy Rule; this may include disclosure to the WTC Health Program Scientific/Technical Advisory Committee (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).

I am writing to ask that you reconsider adding Lupus / Autoimmune diseases to the list of covered diseases related to the WTC health coverage. Let me start off by introducing myself I'm

I am a member of

. I was deployed by : arriving to assist with the search and recovery efforts. Within a few weeks of returning home I began have medical issues as did most responders. Over the years I continued to have increased fatigue, stiffness and joint pain, over reactive reflexes along with numerous other systems that I couldn't explain. In 2011 I was referred to a neurologist with the thought that I possibly had MS after several months of testing it was determined that I had some type of connective tissue disease and was referred to a rheumatologist where it was determined that I have Lupus and Rheumatoid Arthritis (RA). Being a yr old Caucasian male with no family history of autoimmune disease, the Doctors were puzzled. How does a yr old Caucasian male develop Lupus? After explaining my history of being at the WTC during 9/11 and the fact I was exposed to several unknown chemicals along with the silica and mercury they felt it was very possible the cause. Since being diagnosed on : they still have no other possible cause that they can associate with my diagnosis of Lupus / RA.

There have been several studies relating autoimmune disease to WTC first responders. Yet it still is not listed by NIOSH and the CDC as a WTC related illness. Below are Facts supporting my belief that my medical issues in particular lupus are relate to my exposures during my time at WTC 4

Lupus is an autoimmune disease that can have devastating effects on the body. It does this by the body attacking its self. 9 out of 10 people diagnosed with Lupus are females between the age of 15 to 40, with African-Americans being 75% more likely to develop Lupus. Hispanics and Asians are also more likely to develop Lupus that Caucasian woman with 10% of the lupus patients being men "As adults, far fewer males than females develop lupus"¹. The most common cause is hereditary related to a family history of lupus. It is also believed that some types of environmental exposure are suspected causes of Lupus. Some of these environmental factors are believed to be from Silica Dust and Mercury, all of which were at high levels on 9/11 WTC Ground Zero. Most of those in medical and research professions will agree that several factors might determine an individual's likelihood of developing lupus. It is believed that some of those factors are Environment related and plays and important role in the development of lupus. Research is being conducted regarding environmental factors that may play a role in being a trigger for lupus.

"An association between WTC exposure and cancer is biologically plausible, because some contaminants in the WTC dust, such as polycyclic aromatic hydrocarbons, polychlorinated biphenyls, and dioxins, are known carcinogens. Although some contaminants could cause cancer directly, WTC exposure could also trigger chronic inflammation, through microbial infections, autoimmune diseases, or other inflammatory disorders, all of which have been reported as factors in oncogenesis, both experimentally and epidemiologically.

We believe the observed relative excess in cancer cases in WTC-exposed firefighters was unlikely to be the result of non-WTC firefighting exposures, because since 9/11, structural fires have decreased, personal protective equipment has improved, self-contained breathing equipment use has increased, and smoking rates in firefighters have declined.
(conclusion) Our findings support continued monitoring of firefighters and other WTC-exposed cohorts to fully assess cancer risk related to these unique exposures."⁵

In a recent study performed by Mark Farfel, ScD, Director, WTC Health Registry "The WTCHR, a prospective cohort of 71,434, has collected three waves of data (2003-2012) on physical and mental health status, sociodemographic characteristics and 9/11-related exposures. In May 2014, web and paper surveys were sent to 2,786 enrollees who reported post-2001 rheumatoid arthritis or other autoimmune diseases at the Registry's Wave 3 survey (2011-2012). The questionnaire was based on the Connective Tissue Disease Screening Questionnaire, and also queried general health status, medication use, and family history of autoimmune disease.

Results: After one month of data collection, 1,230 (44%) responses had been received. Among web responses (n=453), 155 reported physician-diagnosed rheumatoid arthritis, and an additional 145 screened positive as potential rheumatoid arthritis cases."⁷

This study shows that a high percentage of respondents (24%) have either been diagnosed or test positive for the potential of having autoimmune related disease. It is estimated that 1.5 million people in the US have Lupus which equates to about half a percent of the 71,434 register in the health monitoring 2,786 have reported some type of autoimmune related issue or 3.9 % that is far higher rate than in the general public.

This is just a few of the references available relating Auto Immune Diseases to exposures at WTC/911 and environmental exposures. I realize there have been studies done that presented facts relating Auto Immune Diseases to WTC/911 and you wanted more evidence; however there are several of us out here with issues that aren't being included in studies since we don't live in the New York area. I ask that you reconsider your stance on adding Lupus/Auto Immune as and illness that is related to WTC/911 exposures.

References:

1. <http://www.lupusny.org/about-lupus/who-gets-lupus>
2. <http://www.mollysfund.org/2014/03/what-causes-lupus/>
3. <http://www.hopkinslupus.org/lupus-info/lupus/>
4. http://www.fdnymretirees.org/911_Info/WTC_Centers/wtc_centers.htm
5. <http://www.medicalnewstoday.com/articles/234030.php>
6. <http://consumer.healthday.com/senior-citizen-information-31/misc-arthritis-news-41/ground-zero-workers-at-risk-of-autoimmune-diseases-study-697581.html>
7. <http://www.cdc.gov/wtc/proceedings.html>

Other Environmental Factors

Evidence from human and experimental studies suggests a possible role for exposure to heavy metals such as mercury, hydrocarbons, and solvents. In one study, occupational history of work with mercury or work in a dental office was linked to a higher risk of lupus compared to population controls. A recent study also described a cluster of lupus cases in residents living near an oil field waste site contaminated by mercury. Development of multiple autoantibodies and acceleration of renal disease has also been seen in experimental studies in mice exposed to mercury, cadmium, and lead.

The hydrocarbon pristane has been extensively studied as a cause of lupus-like disease in animal models, including recent findings showing a female predominance in pristane-induced autoimmunity and mechanisms by which pristane may break immune tolerance through increased programmed cell death. No case-control studies have specifically addressed pristane exposure in relation to lupus risk, though pristane levels were also elevated in the oil field waste study mentioned previously. Another recent study showed increased rates of lupus in relation to specific genotypes and proximity to hazardous waste sites likely contaminated with volatile organic waste compounds, but whether pristane or related contaminants specifically played a role could not be determined. However, several experimental studies have shown immune-related effects with exposure to the solvent trichloroethylene or some of its metabolites, in drinking water or by intraperitoneal injection. Two human case-control studies showed no association with the broad category of occupational solvent exposure and lupus, though an earlier study showed increased symptoms of lupus and autoantibodies related to possible low-level exposure to trichloroethylene in water.

One human study has shown an association between high levels of occupational pesticide exposure (mixing) and lupus, while another study of a community with high level pesticide exposures and elevated lupus showed no association between lupus and pesticide levels in the blood. In recent experimental studies, however, exposure to estrogenic organochlorine pesticides was associated with accelerated features of autoimmune disease in lupus-prone mice. Effects were not clearly due to pro-estrogenic mechanisms, however, it should be noted that the role of exogenous female hormones in lupus is not well established. Nevertheless, given their abundance in the environment and effects at very low levels of exposure, xenoestrogens or other environmental contaminants with hormone disrupting or mimicking effects, remain plausible and relevant candidates for study in relation to the increasing incidence and disparities in lupus.

Smoking has been also been identified as an independent risk factor for lupus and other autoimmune diseases. A meta-analysis of several studies, however, showed that only current smoking was associated with a modest increase in risk of lupus. Given the well known role of smoking in inflammation and development of heart disease, smoking is a plausible risk factor and could be considered as a potential risk factor for lupus-related cardiovascular outcomes. More persuasive epidemiologic studies are needed to support a role for hydrazines, aromatic amines and environmental endocrine disrupters – synthetic and naturally occurring chemicals that affect the balance of normal hormone functions in animals.

The effects of ambient air pollution or passive smoking on lupus risk or severity may also be areas of interest in lupus research since findings in support of these hypotheses have been reported for other autoimmune diseases, such as type-1 diabetes, and indirectly through the association of maternal smoking and juvenile rheumatoid arthritis. Silica and past smoking are examples of exposures best studied through the use of carefully designed and validated questionnaires. Studies that provide consistent and rigorous exposure data would enable meta-analyses and provide the large combined samples required for studies of gene-environment interactions. Biomarkers may be useful to confirm exposures to agents that accumulate in the body (e.g., pesticides and metals).

Early life exposures may "program" the immune system and thereby alter susceptibility to a later onset of lupus, for example as proposed for diseases such as asthma and allergy. These exposures may include organic dusts, infections, or exposures that modulate the response to early life infections. Modeling these effects would take careful examination of recalled data in conjunction with coded records (e.g., birth-weight). Longitudinal cohort studies are unlikely to be as effective in studying early life factors and lupus as they have been for more common conditions.

Similar to the differences between lupus genetics in animals and humans, exposures that trigger lupus in animals and people may also differ. Although broadly searching for agents related to the development of lupus in mice may help in identifying such agents for humans, experimental studies should also be concentrated on exploring the role of exposures identified in human studies (e.g., silica, solvents, or pesticides). Experimental studies may be useful when investigating mechanisms involved in both the genetic and environmental causes of lupus. Animal models may also be useful in examining *in utero* or early life environmental exposures in relation to disease risk in off-spring.

Crystalline silica

Crystalline silica is a widely studied occupational risk factor for pulmonary inflammation and fibrosis (silicosis), and has well-known inflammatory effects *in vitro* and *in vivo*. A growing body of literature supports a role for silica exposure as a lupus risk factor. Studies of workers with exposure to crystalline silica have shown 10-fold higher than expected rates of lupus and other systemic autoimmune diseases compared to expected rates in the general population. Two recent studies of lupus patients have also shown higher prevalence of silica exposure in cases compared to population controls. These data are compelling given the consistent association of silica exposure with disease in different populations and using different study designs. They are also consistent with a large body of research showing an association of silica and other systemic autoimmune diseases (e.g., scleroderma and rheumatoid arthritis).

The findings of an association between silica and lupus are also supported by experimental studies that demonstrate that silica both acts as an immune adjuvant (a non-specific stimulant) and contributes to the loss of tolerance through effects on apoptosis in accelerating lupus pathogenesis in lupus models. Although silica is unlikely to account for a majority of lupus cases in the population, it illustrates potential mechanisms by which other exposures might act to trigger or accelerate development of lupus.