
Appendix C: Data Sharing Plan

C.1 Introduction

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) established the World Trade Center (WTC) Health Program within the Department of Health and Human Services. The WTC Health Program's primary goals are to provide monitoring and treatment services to eligible WTC responders. The New York Fire Department (FDNY) is one of seven Clinical Centers of Excellence (CCEs) that provide medical monitoring examinations, diagnosis, and treatment services for WTC-related health conditions.

The FDNY CCE provides comprehensive physical and mental health services to all active and retired FDNY members who responded to the 9/11 attacks. This includes the management and storage of the medical records of approximately 26,000 members (active and retirees).

The Zadroga Act also includes a provision for clinical data collection and analysis. FDNY is one of three Data Centers (DCs) that provide this service. The FDNY DC is required to provide data for research projects that have been and will be funded in response to Funding Opportunity Announcements published by the National Institute for Occupational Safety and Health (NIOSH).

Releasing and sharing data across the wider research community has many advantages, including improvements in data quality, greater understanding of diseases and conditions affecting the public health, and the building of trust and confidence in the data, which are open to review and critique by other researchers and the public. WTC Health Program data are readily accessible to authorized parties per the terms of this Data Sharing Plan.

C2. Source Of Data

Recognizing the potential for long-term health consequences from the exposures experienced at the WTC site, the FDNY WTC Program expanded its initial screening programs to include long-term monitoring, disease surveillance for late-emerging problems, and treatment. As of September 30, 2010, over 15,400 FDNY WTC rescue workers have had medical monitoring examinations. Outreach activities continue in an effort to give monitoring examinations to all of the approximately 16,000 members with whom the FDNY WTC Program has been in active contact. Monitoring and treatment take place at the FDNY Headquarters clinic and at four satellite clinics throughout the Tri-State Area. WTC Health Program members receive free treatment and medications for WTC-related conditions in the following categories: upper and lower respiratory, aerodigestive, ENT, gastrointestinal, and musculoskeletal. The WTC Health Program plans to share data for only WTC-related health research studies.

C.3 Description of Data

WTC members are given monitoring exams on a yearly basis. The exam involves several sections: vitals, PFT, ECG, hearing, physical health survey, mental health survey, blood work/urine, and doctor exam. Physical and mental health surveys have been developed to assess the long-term physical and psychological impacts of 9/11.

Data sets are available for vitals, pulmonary, hearing, fitness, and lab data as well as demographic variables of the first responder cohort, including exposure status (grouped by arrival time/date), smoking status, class (civilian, fire fighter, EMS), duty status (active or retired), race, gender, and age on 9/11.

The variables collected as part of the WTC Health Program in treatment and monitoring have been selected so as to provide as much useful information as possible to users of the data sharing while still protecting the identity of our members according to HIPAA and NIH regulations. Data will not be shared on groups where it is possible to identify the individual group members (e.g., the group of female firefighters exposed to the WTC). All public access data will be completely HIPAA de-identified, as all 18 HIPAA-specified personal identifiers will be removed from publicly released data. Restricted access or limited data sets may include some identifiers (e.g., elements of dates, city, town, state, and ZIP codes, as well as unique codes or identifiers not listed as HIPAA-direct identifiers). In the rare circumstances in which limited or public access data sets are shared which have high potential of resulting in patient identification, a Business Associate Agreement may also be required by the FDNY WTC Health Program Data Center and the research entity.

C.4 Sharing Data

In accordance with the Zadroga Act, FDNY will make data collected, such as that described above, available to health researchers and others in full compliance with the CDC/ATSDR Policy on Releasing and Sharing Data. Data collected through the WTC Health Program will be made available to the public within 1 year after the data have been evaluated and determined to be of the highest quality in terms of completeness, validity, reliability, and reproducibility. The lab values, test results, and demographic information described above will make up the analytical data set to be used for research. In accordance with the Request for Proposal, FDNY will include in its monthly Data Center report an update on the status of the analytical data set in terms of date through which data are available and the completeness of data available for research. Any and all data (de-identified) will be made available in an electronic format for the WTC Program Administrator, should this be requested.

C.5 Requests for Public Use Data

The public use analytical data set will be available to the public and other researchers through a public access website. RTI International, in Research Triangle Park, North Carolina will host the website, but all data will be housed with FDNY.

Researchers requesting public use data must provide the following to FDNY:

- name and title,

- place of employment,
- academic affiliation,
- phone and e-mail,
- name of project with web link if available,
- IRB approval, exemption determination, or not research with human subjects determination/policy,
- name and title of the principal investigator of project,
- a description of the intended use of the data being requested, and
- available funding source and budget for this collaboration.

Every request for public use data will be subject to review by the WTC Health Program directors. In the rare circumstances in which public use data sets are shared that have high potential of resulting in patient identification, a Business Associate Agreement may also be required by the FDNY WTC Health Program Data Center and the research entity.

To facilitate accurate and useful interpretation of publicly released data, FDNY will include documentation of the following items with the release of new data:

- conditions under which data were collected, what the data represent, the extent of the data's completeness and accuracy, and any potential limitations for use;
- information that will preclude misinterpretation of data; and
- instructions that non-CDC data users must agree not to link data with other data sets and instructions to report to CDC and NIOSH any inadvertent discover of the identity of any person and to make no use of that discovery.

C.6 Request for Restricted Access Limited Data Sets

If it is determined that restricted access limited data sets should be made available to researchers, additional requirements will be required to ensure the protection of participants' data.

Researchers requesting restricted access limited data sets must provide the following information to FDNY:

- name and title,
- place of employment,
- academic affiliation,
- phone number and e-mail,
- name of project and web link if available,
- documentation of IRB approval,
- name and title of the principal investigator of project,
- the source and amount of budgetary support you have for this project,
- a description of the intended use of the data being requested, including a rationale for why a restricted access limited data set is required,

- data security provisions in place at the recipient institution and documentation that these provisions meet the requirements specified by FDNY for release of restricted data, and
- initiation of a limited data set agreement that is in compliance with the required terms as specified by HIPAA and includes appropriate penalties for breaches of those terms.

Every request for restricted access limited data will be subject to review by the WTC Health Program directors.

The receiving institution will generally be an institution of higher education, a research organization, or governmental agency, and will have a demonstrated record of using sensitive data according to the highest ethical research standards. Data sharing agreements (i.e., Data Use Agreement) will be used to allow researchers access to sensitive data or restricted use data sets that contain potentially identifiable data and thus would not be included in a public use data set. The data use agreement would specify the requirements that researchers must meet and the restrictions placed on the use of the data to ensure adequate protections for research participants and would be in compliance with the required terms for a limited data set agreement as specified by HIPAA. In the rare circumstances in which limited data sets are shared that have high potential of resulting in patient identification, a Business Associate Agreement may also be required by the FDNY WTC Health Program Data Center and the research entity. As with public use data set releases, appropriate documentation will also be provided with each release to facilitate accurate and useful interpretation of restricted access limited data set releases.

FDNY will disseminate any and all data collected under the WTC Health Program in a timely manner, with complete and accurate data, in order to facilitate the broader community's research and in full compliance with CDC/ATSDR Policy on Releasing and Sharing Data, HIPAA, and other applicable rules and regulations.