Requirements for Data Sharing Requests

The Survivor Data Center (SDC) is committed to enhancing the scientific understanding of health outcomes resulting from the World Trade Center disaster. Sharing data with the research community has many advantages, including a greater understanding of diseases and conditions affecting the Survivor cohort, and improvement in diagnostic and treatment protocols for patients.

As a part of the WTC Health Program, the SDC 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). Limited data set may also be provided to researchers outside of NIOSH funding opportunities, with appropriate IRB-approval and a signed Data Sharing Agreement.

Please see the description below for acquiring either de-identified data or data containing protected health information (PHI). If you are interested in obtaining data, please submit a preliminary Data Request inquiry. All inquiries are reviewed by the SDC Research Oversight Committee.

De-identified Data
Requests for de-identified data require the following steps:

1. Investigators requesting data will be asked to submit a formal request to the WTC EHC Medical Director describing the data requested and outlining the purpose of the study.

2. All requests will be reviewed by the WTC EHC Research Oversight Committee (ROC). The committee is led by the Director of the WTC EHC Special Analytics team. The ROC includes the Medical Director, the SDC, and WTC EHC researchers. The Survivor Data Center Administrator will maintain records of all requests and the status of the requests.

3. Researchers will be required to enter into a Data Use Agreement, which will include requirements to protect participants' privacy and data confidentiality. The recipient will be prohibited from transferring the data to other users and will require that the data be used for research purposes only.

4. Once approved by the ROC, and with an approved Data Use Agreement, the request will be shared with SDC. The DC Administrator will prepare the data and supporting documentation.

   a. Data will be shared as completely and accurately as possible. The WTC EHC follows recommendations set forth in the CDC's operational policy titled "Policy on Public Health Research and Non-research Data Management and Access," which recognize that investigators who collected the data may benefit from first and continuing use. As such, for datasets generated for research, data will not be shared until investigators have received an acceptance from a peer-reviewed publication of the main findings from the final dataset, or within twenty-four months after the end of data collection, whichever comes first. Surveillance data will be available six months

after the end of the calendar year to allow for data cleaning and quality assurance. Data will be provisioned within 60 days of request.

Data Containing PHI

Requests for data containing PHI require the following steps:

1. Researchers should seek Institutional Review Board (IRB)-approval from their home institution prior to requesting data.

2. Researchers who seek access to individual level data will be required to enter into a Data Use Agreement, which will include requirements to protect participants' privacy and data confidentiality. The recipient will be prohibited from transferring the data to other users and must meet the requirement that the data be used for approved research purposes only.

3. In addition to IRB activities, investigators requesting data will be asked to submit a formal request to the WTC EHC Medical Director describing the data requested and outlining the purpose of the study. This can happen concurrently with the IRB approvals.

4. Once all approvals have been granted, the SDC Administrator will prepare the data and supporting documentation.

    a. Data will be shared as completely and accurately as possible. The WTC EHC follows recommendations set forth in the CDC's operational policy titled "Policy on Public Health Research and Non-research Data Management and Access," which recognize that investigators who collected the data may benefit from first and continuing use. As such, for datasets generated for research, data will not be shared until investigators have received an acceptance from a peer-reviewed publication of the main findings from the final dataset, or within twenty-four months after the end of data collection, whichever comes first. Surveillance data containing PHI will be available six months after the end of the calendar year to allow for data cleaning and quality assurance. Data will be provisioned within 60 days of request.

5. Data containing PHI will be limited to WTC EHC members who have provided consent to participate in internal or external research activities. Data from members who declined participation will be excluded; data documentation will note how many non-consented members were excluded from each data set prepared.

Protection of Privacy, Confidentiality, and Security

Data sharing will adhere to HIPAA regulations, NYC H+H policies and will be governed by the NYU IRB.

- Human Subjects and Privacy Issues: The rights and privacy of human subjects who participate in the WTC EHC research will be protected at all times. Prior to sharing, data will be redacted to strip all identifiers to minimize risk of unauthorized disclosure of personal identifiers.

- Scientific practice: Before any data are released/shared, all phases of data collection, transmission, editing, processing, analysis, storage, and dissemination will be evaluated for quality. Preliminary data from a research project may be shared with outside partners for

quality assessment but not for publication. Personnel who share data for quality assessment must follow procedures that are consistent with confidentiality agreements and other constraints.