

DATA AND/OR SPECIMENS USE AGREEMENT
Fire Department of New York
Release of WTC Data

Data and/or specimens that are obtained or used for research is confidential and must be used only for statistical reporting or research purposes. Therefore, it is necessary to insure, to the extent possible, that any use of such data be limited to research by legitimate researchers, and in accordance with applicable laws and this Data and/or Specimens Release Agreement (Agreement). Before research data and/or specimens ("Data") can be released, the Provider of the Data and/or specimens and the Recipient of the Data and/or specimens must agree to several provisions.

This Agreement to share data and/or specimens is between the following parties:

Provider of the Data &/or Specimens (Releasing Institution): Fire Department of New York WTC Program

and

Recipient of the Data &/or Specimens (Institution Receiving Data):

A. RECIPIENT, PROVIDER AND DATA INFORMATION

1. Information about the Researcher who is requesting the Data &/or Specimens (Recipient Researcher):

Signature

Date

Name of Researcher at Recipient Institution (printed or typed)

Institution/Organization

Address

Telephone No.

FAX No.

E-mail address

2. Data and/or specimens being requested:

Data and/or specimens are being requested from the World Trade Center Clinical Center of Excellence database/program maintained by the Fire Department of New York. Additional information about this database may be obtained through [Dr. David Prezant]. He can be reached by phone at [718-999-2696] or by e-mail at [prezand@fdny.nyc.gov].

3. Types of Data &/or Specimens being requested and the portion of the study population from which the Data &/or Specimens were collected.

Data Requested:

4. Are any direct identifiers (e.g., name, address, telephone numbers, Social Security numbers, medical record numbers) or sensitive indirect identifiers (e.g., date of birth, zip code, State, etc.) included in the Data &/or Specimens being requested?

Direct Identifiers	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Indirect Identifiers	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

<p>If Yes to Direct Identifiers, list the direct identifiers that are included in the Data:</p> <p>If Yes to Indirect Identifiers, list the indirect identifiers that are included in the Data:</p>

5. Proposed use and analysis plans for the Data &/or Specimens.

Proposed Uses and Analysis:

6. Safeguards (administrative, technical, physical) that will be used by the Recipient to protect the confidentiality of the Data &/or Specimens.

Safeguards to protect the confidentiality of the data:

7. List of Individuals, Groups, or Classes of Persons who will have access to or use the requested Data and/or specimens at the Recipient Institution, including the principal Researcher (named in Item 1).

NOTE: Data and/or specimens may not be shared with researchers outside the Recipient Institution through this DUA. Researchers at other Institutions must establish their own DUA with FDNY to access these Data &/or Specimens.

Identity of persons with Data access at the Recipient Institution (name, position, phone number, e-mail) :

8. Time period for which Data and/or specimens are being requested.

Requested date of Data release to you: _____
Estimated date of Data return or destruction: _____

B. TERMS AND CONDITIONS

By receiving the Data and/or specimens described above from the Provider, the Recipient agrees to the following:

1. Recipient certifies that the statements made in this Agreement (above) regarding the planned use of the Data and/or specimens are complete and accurate.
2. Recipient will not use the Data and/or specimens for purposes other than described in this Agreement and as approved by the Recipient's IRB.
3. Recipient will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data, and to prevent unauthorized use or access to the Data and/or specimens.
4. Recipient will not disclose Data nor permit others to use the Data and/or specimens except as described in this Agreement. Within the recipient's institution or organization, access to the Data and/or specimens shall be limited to the minimum number of individuals necessary to achieve the purpose stated in the Agreement.
5. No findings or information derived from the Data and/or specimens may be released if such findings contain any combination of data elements that might allow for identification or the deduction of a study participant's identity.

6. In the event the Recipient discovers or is able to deduce the identity of a specific participant, Recipient agrees not to reveal the participant's identifying information nor any associated information in the Data and/or specimens to non-authorized persons nor attempt to contact these individuals.
7. Recipient agrees to subject any findings or manuscripts proposed for public release (e.g., abstracts, presentations, publications) to a stringent review by FDNY WTCHP Data Center Director to assure that data confidentiality is maintained, that individual study participants cannot be identified, and that FDNY review the publication to ensure that the source of data is accurately described, results properly interpreted, its nature understood and if necessary that ample time is provided for FDNY to prepare for its publication. *No data or results can be disseminated, published or publicized without the specific approval of the FDNY WTCHP Data Center Director.*
8. Recipient will report immediately to the Provider and the appropriate institutional Research Review Board (IRB) any use or disclosure of the Data and/or specimens other than as permitted by this Agreement, and will take all reasonable steps to mitigate the effects of such improper use or disclosure, cooperating with all reasonable requests by the Provider towards that end.
9. Recipient agrees that in the event that the Provider determines or has a reasonable belief that Recipient has violated any terms of this Agreement, the Provider may terminate this Agreement and require that the Recipient return the Data and/or specimens and all derivative files. Provider may also seek injunctive relief against Recipient to prevent any disclosure of Data and/or specimens by Recipient to other than the Provider. Recipient understands that as a result of this determination or reasonable belief that a violation of this agreement has occurred, Provider may also refuse to release further data to Recipient. In addition, Provider will report any misuse or improper disclosure of Data and/or specimens as required by applicable laws.
10. Upon completion of the research or the date of Data and/or specimens return specified in box A.8 above whichever comes first, Recipient agrees to destroy the Data and all derivative data sets and samples (after receiving permission from the Provider) or where directed by the Provider to return the Data and/or specimens to the Provider per their instruction. Recipient will be required to certify such destruction or return by signing and returning to the person specified by the Provider on this form (i.e., the FDNY Contact Person listed in A.2 above) a Certificate of Data and/or specimens Return or Destruction provided by Provider.
11. If the Researcher leaves the employ of the Recipient, Recipient will notify the Provider in writing at least 14 days before the Researcher leaves. Researcher is not permitted to take the Data or any derivative data sets and/or specimens with them. Return or destruction of the Data and all derivative data sets and/or specimens as specified in item B.10 above is required by the Researcher's departure date. If continued use of the Data and/or specimens is needed by the institution, then Recipient must specify this in their notification of Researcher leaving and request a revised Data and/or specimens. Use Agreement with a new Researcher. Provider will notify Recipient if the request is accepted and specify procedures to revise the Data Use and/or specimens agreement. If the Researcher would like to continue the use of the data then a new Data and/or specimens Use Agreement will have to be put in place with the Researcher's new institution.

12. If Recipient requires use of the Data and/or specimens or any derivative data sets beyond the date specified in box A.8 above as the Date Data and/or specimens to be returned or destroyed, then Recipient must request a revision to this date in writing at least 30 days before the return or destroy date and specify the reasons for needing the revision.
13. Either party may terminate this Agreement upon thirty days written notice. Upon termination of this Agreement, Recipient will return or destroy, at the Provider's instruction, all copies of Data or portions thereof in its possession that were received from the Provider or created (or had others create) using Data and/or specimens received from the Provider
14. This Agreement shall be construed in accordance with the laws of the State of New York, and in a manner that supports compliance by Recipient and Provider with all applicable requirements of HIPAA (Health Insurance Portability and Accountability Act), and the Privacy Act of 1974.
15. The Terms and Conditions of this Agreement are for the sole benefit of Recipient and Provider and do not create any third party beneficiary rights.

C. Has this protocol been approved by the Provider's and Recipient's IRB

IRB for the Provider _____	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
IRB for the Recipient _____	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

D. Signatures and Clearance for PROVIDER Institution (FDNY): FDNY Researcher, FDNY WTC CCE Medical Director and FDNY DC Medical Director

The signatures below indicate that FDNY agrees to release the Data and/or specimens to the Recipient under the above stated provisions.

1. Signature of FDNY Researcher Responsible for this Data and/or Specimens Release

Signature	Date
Name of FDNY Researcher Releasing Data (printed or typed)	
Institution/Organization	
Telephone No.	E-mail Address.

2. Signature of FDNY Researcher Responsible for this Data and/or Specimens Release

Signature Date

Name of FDNY Researcher Releasing Data (printed or typed)

Institution/Organization

Telephone No. E-mail Address.

3. Signature of FDNY Researcher Responsible for this Data and/or Specimens Release

Signature Date

Name of FDNY Researcher Releasing Data (printed or typed)

Institution/Organization

Telephone No. E-mail Address.

D. Signatures for Use of Data and/or Samples from RECIPIENT Institution

1. Signature of Researcher from RECIPIENT Institution

On behalf of the the Recipient Institution, the undersigned researcher hereby attests that he or she is authorized to legally bind the Recipient Institution to the terms of this Agreement and agrees to all the terms specified herein.

Signature Date

Name of Official from Recipient Institution (printed or typed)

Institution/Organization

Telephone No. E-mail Address