New York City Department of Health and Mental Hygiene
World Trade Center Health Registry

Application for External Researchers
November 2019

Introduction to the External Research Application

Background

The World Trade Center Health Registry welcomes proposals for new studies from external researchers. Researchers may complete and submit an application to request de-identified survey data and/or request that the Registry facilitate recruitment of enrollees into the researcher's study. Applications are restricted to projects whose purpose is to support 9/11-related medical, or public health or other scientific research.

All applications are reviewed by the seven-member WTC Health Registry's External Review Committee, which consists of representatives from the Registry's scientific, community, and labor advisors, the New York City Department of Health and Mental Hygiene (DOHMH), and the federal Agency for Toxic Substances and Disease Registry. The External Review Committee reviews applications for scientific value and the expected contribution to study participants and the community. If the application is approved, the Registry will provide a letter of support for the external researcher's grant application, upon request.

How to Apply

1) Researchers are encouraged to visit the *Research Opportunities* page of the NYC 9-11 Health Info website for additional information regarding the Registry, including publications, general information about our enrollees, and data tools available to researchers (e.g., in-depth information on WTCHR data type and availability). Visit: https://www1.nyc.gov/site/911health/researchers/research-opportunities.page
2) We recommend that researchers contact the Registry to discuss your ideas prior to submitting an application. Call (866) 692-9827 or e-mail **wtchr@health.nyc.gov** and ask to speak with (or request that your e-mail be forwarded to) the Registry's Director of Research.
3) Complete and submit the application and other required materials described in this document. This application is a fillable PDF.

Researcher's Responsibilities

1) Approved researchers will be required to sign a Data Use Agreement with DOHMH.
2) After approval, the project should be submitted to the researcher's Institutional Review Board (IRB), and depending on the project, it may need to be submitted to the DOHMH's IRB. Copies of the IRB approval(s) and annual renewals should be sent to the Registry contact. See page 7, Item 7 (IRB) for additional information regarding which projects require DOHMH IRB submission.
3) Approved researchers are required to submit a short annual report to the Registry that includes publications, resulting from the study, updated IRB approval letter(s) and any graduate theses resulting from the approved research project.
4) The researcher is required to pay for fixed postage to recruitment letters mailed by Registry staff (if applicable).

Financial Support

The Registry does not provide financial support to external researchers. However, we may provide in-kind support to approved projects.

Timeline

1) An acknowledgement e-mail will be sent to the researcher within a week of submission of the application.
2) Applications are reviewed by the External Review Committee typically within 4-6 weeks of receipt.
3) An e-mail with the committee's decision will be sent to the researcher within a week of the committee meeting.

Registry Facilitated Recruitment

1) Registry staff will manage Registry-facilitated recruitment of enrollees into approved research projects.
2) If multiple approved external research studies request to recruit subjects from the same enrollee subpopulation, the Registry will manage recruitment efforts to these enrollees. Typically, enrollees will be contacted with information about only one study at a time.
3) Registry-facilitated recruitment typically involves one or more of the following activities by Registry staff to the group of enrollees identified to receive the approved external research study information, depending on Registry resources and other commitments.
    a. Letters and/or emails with informational materials about the external research study. These communications may also include the study's informed consent document and/or the Registry's standard consent form for release of the enrollee's Registry survey data to the external researcher.
    b. Telephone calls.
    c. Door-to-door outreach. If door-to-door outreach is conducted, the procedures described in the Registry's NYC DOHMH's IRB-approved Door-to-Door Outreach protocol will be followed.
    d. In all of these communications, Registry enrollees will be instructed to either contact the external researcher's study staff directly and/or to contact Registry staff. Enrollees will be informed that their participation is voluntary.

Other Information

1) All data that is sent from the WTCHR will be transferred via BISCOM, typically in SAS format. Alternative formats are available.

2) Collaboration with the WTCHR is neither encouraged nor discouraged; this will not affect your application.

Keywords/Terms

WTCHR: World Trade Center Health Registry

PUDs: Public Use Datasets. There is a de-identified PUDS dataset for each of the Registry's four surveys posted on the 9-11 Health Info website. **Visit:** https://www1.nyc.gov/site/911health/researchers/health-data-tools.page

DFUM: Data File User's Manual (DFUM). There is a DFUM for each of the Registry's four surveys posted on the 9-11 Health Info website. **Visit:** https://www1.nyc.gov/site/911health/researchers/health-data-tools.page

BISCOM: is a secure file transfer solution, using SSL and AES 256-bit encryption that DOHMH uses to transmit large, confidential files to our Agency partners. All file transfers are logged, and deliveries are confirmed. The Registry will provide approved researchers with a project-specific BISCOM account as needed at no charge.

APPLICATION PACKAGE CHECKLIST

- ☐ Application (see pages 5-11 of this document)
- ☐ Brief Proposal (a 2 page summary, plus an optional page for references)
- ☐ Curriculum Vitae of Principal Investigator and any co-Principal Investigators (if any)
- ☐ Biosketch(es) of Principal Investigator and any co-Principal Investigators (if any)
- ☐ Draft recruitment letter and informational materials to be sent to potential study participants (if applicable)
- ☐ IRB approval letter from study PI's institution (if available)

Contact Information

If you have questions about the World Trade Center Health Registry that are not covered in this application, please contact:

World Trade Center Health Registry
New York City Department of Health and Mental Hygiene
Gotham Center
42-09 28th Street, CN-6W
Queens, NY 11101-4132
Tel: toll-free 866-NYC-WTCR (866-692-9827)
E-mail: ***wtchr@health.nyc.gov***

COVER PAGE: WTC Health Registry – External Research Application

Researcher's Name: _____

Organization: _____

Date: _____

New York City Department of Health and Mental Hygiene (DOHMH)
World Trade Center Health Registry
Application Form: Data requests and/or requests for DOHMH to inform enrollees about other studies

Date: _____

1. Title of Study or Project: _____
_____

2. Individual and Organization Requesting Use of the WTCHR: (Please attach a current CV and a biosketch for the PI)
Principal Investigator:_____
Title: _____
Organization:_____
Mailing address: street address: _____
City, State, and Zip code: _____
Telephone number: _____
E-mail: _____

3. Co-Principal Investigators (if any): (If there are no Co-PI's, enter "None".) Please attach a current CV and a biosketch for all Co-investigators

Name(s)	Organization(s)	Phone number(s)/E-mail(s)

4. Type of WTCHR Request (check all that apply):

WTCHR de-identified data request	☐	Complete Questions #5-15, and #18-19 below
WTCHR facilitated recruitment: A request for WTCHR to contact WTCHR enrollees with information about the proposed study	☐	Complete Questions #5-14, and #16-19 below
Request for identifiable individual-level survey data (with signed authorization from enrollees)	☐	Complete Questions #5-15, and #18-19 below

5. Funding Source and Level of Funding:

Funding Source and Level of Funding: List the source(s) of funding for the project and this proposed research, the amount of funding received or anticipated from each source, indicate the type of funding support; i.e., grant, contract, cooperative agreement, interagency agreement, other (specify), and note if the funding is current or is pending. If not applicable for this proposed research, please enter "None" in the box below.

Name of Funding Organization(s)	Current/Pending	Have you or will you apply for a NIOSH WTC Health Program grant? (Y/N)	Other grants applied/intending to apply for

6. Summary of Proposed Study Protocol or Project Activities:

Attach a brief summary of your proposed study or project activities. Submitted summaries must include the follow details:

1. Describe the health, public health, and medical, or other scientific problem addressed by your study or project, including the specific aims of your study
2. Provide sufficient detail to describe your study or project, including as applicable how data obtained from the WTCHR will be used and/or specifically what the study participants recruited from the WTCHR will be asked to do
3. Include the WTCHR study population in which you are interested and describe the benefit of this study to the community or individuals involved
4. Demonstrate an understanding of the scientific merit of your proposed study
5. Include a description of the hypotheses to be tested and some background information to support why the study or project is being proposed
6. Include a brief description of your proposed methods and analytic plan

NOTE: The summary should be limited to 4 pages or less, plus an optional page for references. Do not attach your complete study protocol or a longer detailed description of your project. Do include details that will help with the review of your application.

7. Institutional Review Board (IRB) for the Protection of Human Subjects

(As defined by the U.S. Department of Health and Human Services in the Code of Federal Regulations, Title 45, Part 46):

Evidence of a current Institutional Review Board (IRB) approval is required prior to the release of any WTCHR data or Registry-facilitated recruitment and contact of WTCHR enrollees.

If this study or project involves one or more of the following conditions: (1) a request for WTCHR staff to serve as collaborators on the project; (2) a request for identifiable individual-level survey data; (3) WTCHR facilitated recruitment of WTCHR enrollees into the researcher's study, then a current valid IRB approval is REQUIRED from BOTH the applicant's organization AND DOHMH. For conditions #1 and #2, a protocol must be submitted to the DOHMH IRB. For condition #3, all of the project's communications, but not a protocol, must be submitted to the DOHMH IRB for approval.

7a. Does this study have current approval from the study PI's institution's IRB? ☐ Yes ☐ No

7b. If YES, Date of the IRB's approval and attach the IRB letter:

7c. Please provide the following information on the PI's IRB to review this project outside of DOHMH:

Name of the IRB:

IRB's Multiple Project Assurance (MPA) number or Federal wide Assurance (FWA) number:

8. Legal Contact

A legal contact is a person within the PI's institution who will review the legal Data Use Agreement from DOHMH to the PI's institution to assure that all the terms are agreeable to the PI's institution. In some cases, the legal contact is the same person who has the right to sign the legally binding agreement.

Please note: For requests that are limited to facilitated recruitment, a letter of intent written by the study's authors may serve as a legal agreement. However, it is up to DOHMH to determine whether a legal data use agreement is required.

Name of Legal Contact at PI's institution: _____
Title: _____
E-mail: _____
Phone number: _____

9. Federal Certificate of Confidentiality*

9a. Does this study have a federal Certificate of Confidentiality**?** ☐ Yes ☐ No

9b. If NO, will the study apply for a federal Certificate of Confidentiality? ☐ Yes ☐ No

*Required for requests for identifiable individiual-level survey data.

10. Other Uses of the Data

10a. Will any of the information obtained from the WTCHR data, or from the request for Registry-facilitated recruitment to inform WTCHR enrollees about the researcher's proposed study be used as a basis for **legal, administrative, or other actions,** which may directly affect particular individuals or establishments as a result of their specific identification in this project?

☐ Yes ☐ No ☐ Maybe

If *Yes* or *Maybe*, please explain:

10b. Will any of the information obtained from the WTCHR data, or from the request for DOHMH to inform WTCHR enrollees about the proposed study be used as a basis for **marketing purposes**, including, but not limited to, marketing of pharmaceutical drugs?

☐ Yes ☐ No ☐ Maybe

If *Yes* or *Maybe*, please explain:

11. Briefly describe your population of interest:

_____
_____
_____

12. Eligibility groups (Check all that apply and add details regarding age groups, subgroups, etc. as needed):

RESPONDERS (also known as Rescue/Recovery workers)
People involved in rescue, recovery, clean up or other activities at the WTC site, the WTC Operations on Staten Island recovery operations or on the barges that carried debris between these sites, for at least one shift anytime between September 11, 2001 and June 30, 2002. Sub-groups of responders include fire fighters, police, sanitation, construction workers, as well as others.

☐ **All Responders**

☐ **Selected groups of Responders? Please describe:** _____
_____
_____

SURVIVORS. There are four subgroups of survivors, with adults and children in each subgroup. Please select both the subgroup(s) and the age group(s) you are interested in.

☐ **All**

Selected groups of Survivors. Please check all that apply.

☐ **Residents:** People who were living south of Canal Street on September 11, 2001.

☐ **Area workers:** People who were in a building south of Chambers Street on September 11, 2001

☐ **Passers-by**: People who were in the street or on the subway south of Chambers Street on September 11, 2001

☐ **Students/school staff:** Students and staff enrolled or working in schools (pre K-12) or daycare centers south of Canal Street on September 11, 2001

☐ **Other subgroup? Please describe:**
_____
_____
_____

☐ **ADULTS:** On or over the age of 18 on 9/11/2001

☐ **CHILDREN:** Under the age of 18 on 9/11/2001

13. Please describe the inclusion/exclusion criteria that will define your study population:

Inclusion/exclusion criteria type (e.g. age, Post-Traumatic Stress Disorder at Wave 2)	**Variable name** (e.g. name listed in PUDs/DFUM)*	**Description** (e.g. exclude ages 65+)

*****Refer to this link if you have any questions regarding the variables.

14. Each enrollee's preferred language is captured by the WTCHR. Check the enrollee language(s) that you wish to include in your study population.

☐ All **OR** ☐ English ☐ Spanish ☐ Mandarin ☐ Cantonese ☐ Other

15. Please describe the variables you are requesting. (Refer to this link if you have any questions regarding the variables.) (Not applicable for requests that are only for WTCHR-facilitated recruitment.)

Demographic variables (e.g., gender, age, race/ethnicity, household income, education level):

_____
_____
_____

Exposure variables (e.g., dust cloud exposure, present on 9/11/2001 south of Chambers Street):

_____
_____
_____

Mental and Physical Health variables (e.g., symptoms, conditions, mental health screenings):

_____
_____
_____

Other Variables (e.g. geographical variables, other):

_____
_____
_____

16. Attach draft recruitment letter and informational materials to be sent to potential study recipients. (Only for WTCHR-facilitated recruitment requests)

17. Specify the requested mode of DOHMH communication with WTCHR enrollees. (Only for WTCHR-facilitated recruitment requests)*:

☐ Communications about the researcher's study to be e-mailed to enrollees
☐ Communications about the researcher's study to be mailed to enrollees
☐ Both

Note: The WTCHR provides the external researcher with envelopes on which **the external researchers affix postage paid for by themselves**. After postage is affixed, the external researcher will then return the envelopes to the WTCHR, whose staff will then affix the appropriate mailing labels. The WTCHR will then mail out the finalized envelopes.

**There are two other types of communication: (1) phone and (2) door-to-door – but these are only available if funding is received from the external researcher and DOHMH IRB approval is received.*

18. Would you like to receive a statistical breakdown of the population/data you requested?

☐ YES ☐ NO

If YES, Describe the structure of the data that you would like to receive:

☐ Aggregate data; separate frequencies for each variable*

☐ Aggregate data; cross tab frequencies* (specify) _____
_____

*** Note:** to protect the confidentiality of enrollees, external research requests will be accommodated only to the extent that confidentiality of enrollees is protected.

19. Additional Information:

_____
_____
_____
_____

Submission Instructions:

Complete this application by filling it out online. Save this as a PDF then submit it to the Registry's e-mail (wtchr@health.nyc.gov). In the same e-mail, include all additional required documents.