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



Guidelines for External Researchers

May 2005

Overview

The New York City Department of Health and Mental Hygiene (DOHMH) has developed the World Trade Center Health Registry (WTC HR), in cooperation with the federal Agency for Toxic Substances and Disease Registry (ATSDR), to help determine whether there are any long-term physical or mental health effects on persons most directly exposed to the environmental effects of the tragedy of September 11, 2001.

Over 71,000 persons completed an interview and enrolled in the WTC HR between September 2003 and November 2004. Baseline data collection involved a 30-minute telephone or in-person interview. Populations in the WTC HR included: occupants of the 35 damaged or destroyed buildings; residents living south of Canal Street; students and staff in schools (preK-12th grades) or daycare facilities south of Canal Street; rescue, recovery, and clean-up personnel or volunteers at the WTC site, the WTC Recovery Operations on Staten Island, or the barges; and people who were in a building, on the street, or on the subway south of Chambers Street on 9/11/01.

Guidelines

The following guidelines address three types of expected requests from external researchers that pertain to the WTC HR: (1) requests for existing interview data collected from Registry registrants by the DOHMH, (2) requests to facilitate contact with Registrants for enrollment into new studies where DOHMH interaction with Registrants is limited to a single informational letter; and (3) requests to facilitate contact with Registrants for enrollment into new studies that require more extensive DOHMH interaction with Registrants than a single informational letter.

All contact with WTC HR registrants will be conducted by DOHMH and personal identifiers will not be released to external researchers.

All applications shall follow a 2-stage submission process:

1. A short proposal is submitted to the WTC HR Review Committee for review.
2. Once the short proposal is approved by the WTC HR Review Committee, then a more detailed proposal is submitted to the IRB of the researcher's institution (required of all applications) and to DOHMH's IRB (required only for applications that (a) request DOHMH to interact with WTC HR registrants more extensively than with a single informational letter, or (b) request individual level data).

Sharing of WTC HR information is restricted to projects with the purposes of supporting medical, public health and emergency preparedness research or other scientific research. The WTC HR may not be used as a basis for marketing or for legal, administrative, or other actions that may directly affect identified individuals or establishments as a result of their participation in the WTC HR. **If you are in doubt as to whether your application request is appropriate, please contact us prior to submission.**

I. Description of the WTC Health Registry

- a. WTC HR data codebook: The WTC HR project is developing a data codebook. Selected sections of this data codebook will be available to researchers, including the following (at minimum):
 1. Complete list of variables and response codes
 2. Number of registrants (total and for selected subgroups)
 3. Number of registrants who consented to being contacted for future studies (total and for selected subgroups)
 4. Identification of variables and data that will not be released (e.g. confidential, identifying variables, data stratifications with small numbers, etc.)
 5. Description of calculated variables and categorized variables

- b. Pre-application data queries: Researchers may submit a pre-application data request for information on groups of registrants that may not be included in the data codebook. DOHMH project staff will run queries to obtain this information, obtain clearance for sharing this information from the WTC HR Principal Investigator (PI) or designate, and send this information to the researcher to enable them to prepare a research application for submission to the WTC HR Review Committee. Generally, pre-application data queries are anticipated to be requests for minimal information that will enable a researcher to prepare the application. If the data request is deemed to exceed a minimal data query by the WTC HR PI or designate, the pre-application query request will be rejected and the researcher will be advised to submit the data query request as a formal application.

Researchers should submit their pre-application data request to the WTC HR Project Coordinator. If the pre-application data request is cleared, the Project Coordinator will deliver the data within ~ 30 days of approval of the data request (depending in part upon the complexity of the data extracted). DOHMH staff may decline requests or postpone requests until a later date (e.g. the next quarter) if the volume of data queries exceeds internal capacity.

II. WTC HR Application Submission Guidelines

Applications to the WTC HR for access to data or to facilitate contact with registrants will include:

1. A short proposal (described in Section II.e) submitted to the WTC HR review committee.
2. If the proposal is approved by the WTC HR Review Committee, proof of IRB approval from the researcher's institution's IRB must be submitted to the WTC HR Project Coordinator before any further action may be taken.
3. If the proposal requests either: (a) DOHMH to interact with WTC HR registrants more extensively than with a single informational letter, or (b) individual level data (released only with written permission from individual participants), then the researcher must obtain IRB approval from the DOHMH IRB.

- a. WTC HR Review Committee: The WTC HR Review Committee will review proposals for general scientific value and technical merit and will be comprised of seven members, including two public health scientists from DOHMH, one public health scientist from ATSDR, one member from the CAB (Community Advisory Board), one member from the SAC (Scientific Advisory Committee), one member from the LC (Labor Committee), and one member of the DOHMH institutional review board.

Labor–Related Proposals: For proposals that expressly involve unionized populations, a second designated member of the Labor Committee will participate in the review, for a total of eight Review Committee members.

The Review Committee will be selected for a set one-year term, and alternates will be selected for each member on the committee. The SAC, CAB, and LC Review Committee members will be elected by members of their organization. The DOHMH IRB member will be designated by the DOHMH. The WTC HR’s PI shall be the chair of the Review Committee. Any member may serve for more than one year in a row, if selected. If an active member of the Review Committee submits an application, the member shall be excused from reviewing their application and the member’s alternate shall review the application.

- b. Deadline for submission: All applications must be received by the monthly deadline (**the first of the month**). The deadline will be at least 7 days in advance of the scheduled monthly meeting.
- c. Timing of review: All applications received by the monthly deadline will be reviewed at the following Review Committee meeting. A minimum of five members will constitute a quorum for a Review Committee meeting. Applications received after the monthly deadline will be held for review until the next month’s review meeting and will be reviewed within a six week time period. The review committee will hold a monthly meeting or conference call to discuss the applications received. Applications will be distributed to Committee members one week in advance of the meeting.
- d. Submission contact person: The WTC HR Project Coordinator is the designated contact person to receive external applications for the Review Committee and to answer any questions regarding submissions.

Send applications to: Erin Gregg, WTCHR Project Coordinator
 WTC Health Registry
 New York City Department of Health and Mental Hygiene
 125 Worth Street, Room 202, CN6
 New York, NY 10013
 212-442-1585 (PHONE); 212-788-4127 (FAX)
egregg@health.nyc.gov

- e. Application: All researchers must complete and submit an application to the WTC HR review committee. Researchers must submit a separate application for each proposal. (See the separate document, WTC HR Application Form and Instructions.)

The completed Application Form must include at minimum the following:

1. Name(s) of primary researcher(s), title, organization(s), contact information, CV(s) and biosketch(es), along with the name, organization and contact information for all co-PI's.
 2. Specify the type of request:
 - a. WTC HR data request only
 - b. A request to have DOHMH contact WTC HR registrants about the proposed study only
 - c. WTC HR data request plus a request for DOHMH to contact WTC HR registrants with information about the proposed study
 - d. A request to collaborate more extensively with DOHMH on a study protocol
 3. Cost estimate of request and information regarding the study's potential funding source, type of funding support (i.e., grant, contract, etc.), and whether the funding is current or pending. The researcher shall be responsible for funding costs of DOHMH facilitation of contact with WTC HR registrants.
 4. Brief summary of proposed Study Protocol or Project Activities (~ 2 pp), including a brief literature review, a description of the problem addressed or hypothesis tested by the study, the WTC HR study population of interest, a brief description of the proposed methods and analytic plan, a description of the benefit to the community or individuals involved, and a layperson's abstract.
 5. Depending on the type of request, the researcher will complete a Data Request Form and/or an Access to Registrant Form to be included in the application.
 6. Copy of recruitment letter and informational materials to be sent to potential study participants (if applicable).
 7. Checklist
- f. Notification of receipt of application: The WTC HR Project Coordinator will assign a tracking number to each application and will send a letter acknowledging receipt of application to the researcher. The Project Coordinator will check the application for completeness and will return any incomplete applications to the researcher for resubmission.
- g. WTC HR Review Committee review process: Proposals may be rejected by the Project Director without being distributed to WTC Review Committee Members for the following reasons: (1) requests for information (data or access to registrants) that will be used for litigation or marketing purposes (including pharmaceutical marketing); (2) requests for data or access to registrants that are not feasible; (3) data requests for analyses already scheduled to be conducted by DOHMH or ATSDR within the first two years after the end of data collection (similar to the NHANES guidelines); (4) requests for data that involve individual level data without a process for obtaining written authorization from individual participants. The application will be rejected but the researcher will have the option to reapply.

The Review Committee will review and score each application submitted to the group. An application that receives a score lower than a **70 point average** shall be rejected by the Committee. A minimum of five Review Committee

members must participate in the Review Meeting to have a voting quorum. The Committee shall write a brief summary of explanation for each application and shall provide this summary to the Project Coordinator. The Project Coordinator will provide the applicant with this summary (but not the scores).

Scoring Criteria: Scoring criteria included in the scoring include: scientific merit of proposed study or project, technical merit of methodology for conducting study, demonstrated level of relevant experience, adequacy of organizational capacity and qualifications, and contribution of study to community or individuals. A researcher is encouraged to use these guidelines in writing their brief summary of the proposed study or project. The maximum score assigned to a reviewed application will be 100 points.

1. Scientific merit of proposed study or project (30 points)

- Summary demonstrates an understanding of the scientific contribution of the proposed research
- Literature cited supports research hypothesis

2. Technical merit of methodology for conducting study: (30 points)

- Application demonstrates that the WTC HR has a sample that will fulfill the objectives of the proposed study
- Data collection methods are sound, feasible, and incorporate recognized and appropriate approaches
- Analytic plan proposed is appropriate
- Research design incorporates consideration of appropriate controls and measurement of covariates for analyses
- Expected results of proposed study are shown to be capable of delivering findings that will answer study hypotheses

3. Demonstrated level of relevant experience: (20 points)

- The CV(s) and biosketch(es) of the project's PI (and co-PI's, e.g. a faculty advisor) demonstrates the researcher's capacity to conduct proposed research (e.g. prior research projects completed, publications, substantiated expertise in epidemiology, social and behavioral research, demography, statistics or medical research)

4. Funding and organizational capacity: (10 points)

- The organizations identified are reputable and have the capacity to support the proposed research
- Study has identified sources for adequate funding to support the proposed study

5. Contribution of study to community or individuals: (10 points)

- Summary demonstrates a contribution to the community, including the proposed study population or participating individuals

- Study has new or unique merit to the affected community, is not redundant with prior study requests, and is not being conducted on an over-studied registry population
- h. **Notification:** The WTC HR Project Coordinator will send a letter to all researchers who submitted an application for review within a week of the Review Committee meeting to notify them whether or not their application has been approved.

If an application has been approved, an information packet will be sent with the letter. This information packet may, depending on the nature of the study, include instructions on preparing the more detailed proposal for the DOHMH IRB submission and will include information on the upcoming DOHMH IRB deadlines.

If an application has not been approved, the researchers may revise according to comments provided and re-submit the application for consideration at the next Review Committee meeting.

III. Institutional Review Board (IRB) Submission Requirements for WTC HR Applications:

Any external research application that has been approved by the WTC HR Review Committee will require IRB approval from the researcher's institution prior to DOHMH taking any further action.

If the application only involves a data request for de-identified data, then the research study will not require DOHMH IRB review.

If the application only requests that DOHMH contact a subset of WTC HR registrants with information about a proposed study using DOHMH's standard cover letter, then the research study will not require DOHMH IRB review.

However, if DOHMH is actively engaged in recruitment or data collection activities, for example more than one contact attempt with selected registrants, or DOHMH endorsement of the study is in the cover letter, then the application will require DOHMH IRB review.

a. IRB Review and Approval:

1. **External IRB review only:** If the WTC HR application is approved, the researcher shall submit a letter of approval from their institution's IRB once received (and, if relevant, funding approval) to the WTC HR Project Coordinator. The applying institution's IRB must meet Federal regulation standards and have Federal Wide Assurance.

2. External and DOHMH IRB review: If a researcher is requesting DOHMH to contact registrants about their study more than once, or with correspondence other than DOHMH's standard cover letter which states its non-endorsement of the study, or if the researcher is also requesting individual level data on specific Registrants, then the researcher must submit an application to the DOHMH IRB after obtaining IRB approval at their own institution.

- b. Researcher's Agreement: After appropriate IRB approvals have been obtained, if the application is not required to be submitted to the DOHMH IRB, then the researcher signs the Researcher's Agreement with DOHMH that states the agreed use of the data and specifies any limitations. The researcher's agreement shall include a requirement that the researcher submits an End of Study Report. DOHMH shall develop a standard End of Study Report that shall include, at a minimum, the closing report to the IRB(s), the number and a brief description of any adverse events (if applicable), and the study's response rate. If the application is required to be submitted to the DOHMH IRB, then the researcher will fulfill standard DOHMH IRB reporting requirements.
- c. Data Request (if relevant): Using the Data Request Form submitted by the researcher in the application as a guide, the WTC HR Project Coordinator extracts the requested data in the requested format, and makes arrangements for secure delivery of the data. The Project Coordinator will deliver the data within ~ 60 days of approval of the data request, assuming all necessary agreements have been prepared and signed (depending upon complexity of data request).
- d. Access to Registrants (if relevant): Using the Access to Registrant Form submitted by the researcher in the application, the WTC HR Project Coordinator verifies the target population with the researcher. The researcher prepares the required number of study information packets to be sent (via email or mail) to potential study participants and submits these packets to DOHMH along with a check to cover administrative and staff labor costs, per standard cost estimates in the WTC HR Fee Schedule Form. The study information packets shall include the standard cover letter from DOHMH/ATSDR reminding participants that they expressed interest in receiving information about other studies and informational materials. If study information packets are to be mailed to potential study participants, packets shall be submitted to DOHMH in sealed postage-paid envelopes, with the DOHMH return address. DOHMH shall open a randomly selected number of packets to ensure that the mailing conforms to these guidelines. The WTC Project Coordinator shall report the number of undeliverable emails or returned mailed packets to the researcher.

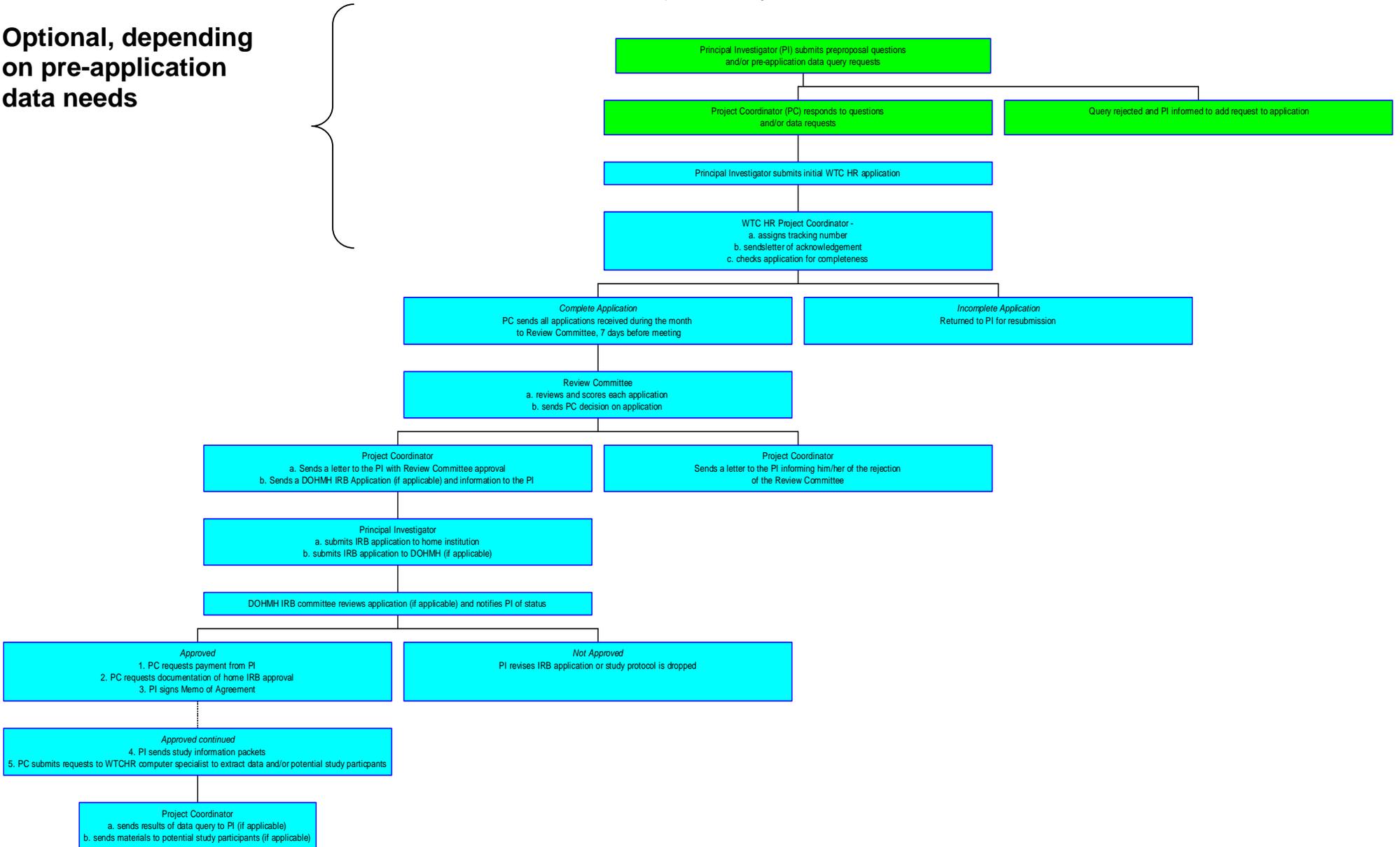
The WTC HR Project Coordinator will prepare the mailing labels (or email list) and mail (or email) the information packets to registrants within ~ 2 weeks of delivery of the information packets to DOHMH.

IV. WTC HR Application Instructions:

1. A separate WTC HR application must be submitted for each study or project.
2. If there are many approved applications, it may take longer to process data requests or requests to inform registrants about additional studies.
3. To expedite the application review process, completed application forms may be e-mailed. A complete signed application package, plus necessary approvals, must be received prior to the release of any data or prior to informing WTCHR registrants about a new study.

Process for External Researchers to Request Data or Inform Registrants about Additional Studies

Optional, depending on pre-application data needs



APPLICATION CHECKLIST

- Application
- Brief Proposal (2 page summary, plus an optional page for references)
- Layperson's Abstract
- Curriculum Vitae of Principal Investigator
- Biosketch(es) of Principal Investigator
- Data Request Form (if applicable)
- Access to Registrant Form (if applicable)
- Copy of recruitment letter and informational materials to be sent to potential study participants (if applicable)

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

Application Form: Data requests and/or requests for DOHMH to inform registrants about other studies

1. Title of Study or Project: _____

2. Individual and Organization Requesting Use of the WTCHR: (Please attach a current CV and a biosketch)

Principal Investigator (or Project Director): _____

Title: _____

Organization: _____

Mailing address: street address: _____

City, State, and Zip code: _____

Telephone number: _____ Fax: _____ Email: _____

3. Co-Principal Investigator (if any):

(if there are no CO-PI's enter "None.")

Name(s)	Organization(s)	Phone number(s)/Email(s)

4. Type of WTCHR Request:

WTCHR data request <u>only</u>	<input type="checkbox"/>	Complete Items #5-10 below
A request to have DOHMH contact WTCHR registrants with information about the proposed study <u>only</u>.	<input type="checkbox"/>	Complete Items #5-9, 11 and #12 below
WTCHR data request <u>plus</u> a request for DOHMH to contact WTCHR registrants with information about the proposed study.	<input type="checkbox"/>	Complete Items #5-12 below

5. Estimated Cost of Requesting, Funding Source and Level of Funding:

Estimated Cost of Request: List an estimate of all costs associated with your data request and/or your request for DOHMH to inform WTCHR registrants about your proposed study. See the attached Fee Schedule to estimate costs.

Funding Source and Level of Funding: List the source(s) of funding for the project and this sample, the amount of funding anticipated from each source, and indicate the type of support provided: i.e., grant, contract, cooperative agreement, interagency agreement, other (specify), and note if the funding is current or is pending.

6. Summary of Proposed Study Protocol or Project Activities:

Provide a brief summary of your proposed study or project activities. Describe the health, public health, medical or emergency preparedness problem(s) addressed by your study or project. Provide sufficient detail to describe your study or project and how data obtained from the WTCHR will be used. Include in this summary the WTCHR study population in which you are interested, describe the benefit of this study to the community or individuals involved, demonstrate an understanding of the scientific merit of your proposed study, include a description of the hypothesis to be tested and some background information to support why the study or project is being proposed, and include a brief description of your proposed methods and analytic plan. **(The summary should be limited to 2 pages or less, plus an optional page for references. Do not attach your complete study protocol or a detailed description of your project.)**

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 DOHMH contacting WTCHR enrollees. If this study or project involves either: 1) a request for DOHMH to interact with WTCHR registrants more extensively than a single informational letter, or (2) a request for individual-level data a current valid IRB approval is REQUIRED from BOTH the applicant’s organization and DOHMH.**

7a. Please provide the following information on the 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:

7b. Does this study have current approval from this IRB? Yes No

7c. If YES, Date of the IRB’s approval:

8. Federal Certificate of Confidentiality

8a. Will this study or project receive a federal Certificate of Confidentiality? Yes No

8b. If YES, has this study already received a federal Certificate of Confidentiality? Yes No

9. Other Uses of the Data

9a. Will any of the information (obtained from the WTCHR data, or from the request for DOHMH to inform WTCHR registrants about the 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:

9b. Will any of the information (obtained from the WTCHR data, or from the request for DOHMH to inform WTCHR registrants 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:

10. Data Access Form attached:

Yes

No

11. Access to Registrant Form attached:

Yes

No

12. Attach copy of recruitment letter and informational materials to be sent to potential study recipients.

ITEM 10: DATA ACCESS FORM

Attachment to WTC Health Registry External Research Application

Title of Research Proposal: _____

Principal Investigator/Project Director: _____

1. Briefly describe the research questions you are trying to answer:

2. Briefly describe your population of interest:

3. Please describe the variables you are requesting. (Refer to the WTC Health Registry Questionnaire if you have any questions regarding the variables.)

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):

4. Type of Interviews (check all that apply):

- Completed Self-interviews (adults)
- Completed proxy interviews by parent/guardian for children (aged < 18 years at time of interview)
- Completed proxy interviews by guardian of mentally incompetent/disabled adults
- Completed proxy interviews for deceased registrants (who died > 9/11/2001; Note: this data excludes health information)

5. **Source of WTCHR Registrants (check all that apply):**

- Self-identified (via WTCHR pre-registration web site or inbound telephone call)
- Identified from a list of potentially eligible registrants

6. **Eligibility groups (check all that apply):**

- Children enrolled in daycare/schools (K-12 grades) south of Canal Street on 9/11/2001
- Staff employed in daycare/schools (K-12 grades) south of Canal Street on 9/11/2001
- Rescue, Recovery, and Cleanup workers and Volunteers at the WTC site, at the WTC Recovery Operations on Staten Island, or on the barges (defined as working at least one shift anytime from 9/11/2001 until 6/30/2002)
- People who were in a damaged or destroyed building (including the WTC towers) on 9/11/2001
- Other people who were on the street, in a building, on the subway south of Chambers Street on 9/11/2001
- Residents whose primary residence was north of Chambers Street and south of Canal Street on 9/11/2001
- Residents whose primary residence was south of Chambers Street on 9/11/2001
- Other (specify) _____

7. **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) _____

- De-identified line listed data* (select if you are interested in conducting your own analyses with line-listed data)
- Other: (specify) _____

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

8. **How would you like the data sent to you?**

Mode: Diskette* Zip Disk* CD-ROM* Electronic File Transfer Protocol (FTP)*

***Note:** all of these files will be password-protected. A password will be sent to you separately.

Format: Excel Spreadsheet SAS output MS Word document
 Flat File, ASCII-comma delimited (only available for line-listed data)

Delivery: US Mail* FedEx Courier pick-up in person FTP DHL UPS

***Note:** Default shipping is US Mail. Additional delivery options are available at the researcher's expense.

9. **Would you like to have contact with other researchers who have done or are planning to do similar research with the WTC Health Registry?** Yes No

If yes, may we give them your email address to facilitate such contact? Yes No

10. Additional Comments:

ITEM 11: ACCESS TO REGISTRANTS FORM

Attachment to WTC Health Registry External Research Application

Title of Research Proposal: _____

Principal Investigator/Project Director: _____

1. Briefly describe the research questions you are trying to answer:

2. Briefly describe your population of interest:

3. Specify the requested mode of DOHMH communication with WTCHR registrants:

- Information packets about the researcher’s study to be emailed to registrants
- Information packets about the researcher’s study to be mailed to registrants
- Both

4. Identify the registrant’s language of interest (language of interview) (check all that apply):

- English
- Spanish
- Mandarin
- Cantonese
- other

5. Please identify the characteristics of the population of interest. (Refer to the WTC Health Registry Questionnaire if you have any questions regarding the variables.)

Demographic variables (check all that apply) (if unchecked, all will be included in sample selected):

- Gender: female male
- Race/Ethnicity: White, non-Hispanic Black, non-Hispanic Hispanic Asian Other
- Age (at time of interview): under 18 18-24 25-44 45-64 65 and older
- Marital Status (at time of interview): married not married, living with partner widowed
 divorced separated never married
- Education Level (at time of interview): never attended school or only attended kindergarten grades 1-8
 grades 9-11 grade 12 or GED college 1-3 years college 4 years or more postgraduate degree
- Employment Status (on 9/11): employed/self-employed not employed
- Household Income (in 2002, in thousands): less than \$10 \$10-<\$15 \$15-<\$25 \$25-<\$35
 \$35-<\$50 \$50-<\$75 \$75-<\$100 \$100-<\$150 \$150-<\$200 \$200 or more
- Residence (on 9/11): Tri-State Area (NY, NJ, CT) New York City only South of Canal Street only
 South of Chambers Street only Other U.S. State(s) (specify) _____ International
- Other (specify): _____

Exposure variables (check all that apply) (if unchecked, all will be included in sample selected):

- Dust or debris cloud exposure: Yes No
- Present south of Chambers Street on 9/11/2001: Yes No
- Present south of Chambers Street anytime from 9/12/2001 to 12/31/2001: Yes No

Present in the WTC towers on 9/11/2001: Yes No
Present in another damaged or destroyed building on 9/11/2001: Yes No
Personally witness one or more traumatic events on 9/11/2001: Yes No
Present on WTC site (“exclusion zone”) on 9/11/2001: Yes No
Present on WTC site (“exclusion zone”) on 9/12/2001: Yes No
Present on WTC site (“exclusion zone”) anytime from 9/13/2001 – 6/30/2002: Yes No
Present at WTC Recovery Operations on Staten Island anytime from 9/12/2001-6/30/2002: Yes No
Present on barge transporting WTC materials anytime from 9/12/2001 – 6/30/2002: Yes No
Worked on the “pile” at the WTC site (“exclusion zone”): Yes No
Resident who left their residence as a result of the WTC disaster: Yes No

Mental and Physical Health variables (check all that apply) (if unchecked, all will be included in sample selected):

Smoker (ever smoked)? Yes No
Current Smoker (at time of interview)?: Yes No
Pregnant on 9/11/2001 (women only)?: Yes No
Probable PTSD (within 4 weeks prior to interview) (based on PCL-CV): Yes No
Probable Serious Mental Illness (within 30 days prior to interview)(based on K6 psychological distress scale):
 Yes No
Injury on 9/11/2001: cuts/abrasions/puncture wound eye injury/irritation sprain/strain burn
 broken bone concussion/head injury/knocked out
Symptoms after 9/11/2001(not necessarily current): wheezing shortness of breath persistent cough
 sinus problems eye irritation throat irritation skin rash or irritation
 hearing problem or loss heartburn/indigestion/reflux
 frequent severe headaches depression/anxiety emotional problems
 other (specify) _____
Conditions after 9/11/2001 (not necessarily current): asthma hypertension/high blood pressure
 coronary heart disease angina heart attack stroke emphysema
 diabetes cancer (specify) _____
 other (specify) _____

Other Variables (specify):

6. Type of Interviews (check all that apply):

- Completed Self-interviews (adults)
- Completed proxy interviews by parent/guardian for children (aged < 18 years at time of interview)
- Completed proxy interviews by guardian of mentally incompetent/disabled adults
- Completed proxy interviews for deceased registrants (who died > 9/11/2001; Note: this data excludes health information)

7. Source of WTCHR Registrants (check all that apply):

- Self-identified (via WTCHR pre-registration web site or inbound telephone call)
- Identified from a list of potentially eligible registrants

8. Eligibility groups (check all that apply):

- Children enrolled in daycare/schools (K-12 grades) south of Canal Street on 9/11/2001
- Staff employed in daycare/schools (K-12 grades) south of Canal Street on 9/11/2001
- Rescue, Recovery, and Cleanup workers and Volunteers at the WTC site, at the WTC Recovery Operations on Staten Island, or on the barges (defined as working at least one shift anytime from 9/11/2001 until 6/30/2002)
- People who were in a damaged or destroyed building (including the WTC towers) on 9/11/2001
- Other people who were on the street, in a building, on the subway south of Chambers Street on 9/11/2001
- Residents whose primary residence was north of Chambers Street and south of Canal Street on 9/11/2001
- Residents whose primary residence was south of Chambers Street on 9/11/2001

Other (specify) _____

9. Would you like to receive a statistical breakdown of the population you requested?

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 registrants, external research requests will be accommodated only to the extent that confidentiality of registrants is protected.

10. (If you replied “Yes” to #9), How would you like the data sent to you?

Mode: Diskette* Zip Disk* CD-ROM* Electronic File Transfer Protocol (FTP)*

***Note:** all of these files will be password-protected. A password will be sent to you separately.

Format: Excel Spreadsheet SAS output MS Word document

Delivery: US Mail* FedEx Courier pick-up in person FTP DHL UPS

***Note:** Default shipping is US Mail. Additional delivery options are available at the researcher's expense.

11. Would you like to have contact with other researchers who have done or are planning to do similar research with the WTC Health Registry? Yes No

If yes, may we give them your email address to facilitate such contact? Yes No

12. Additional Comments:

Fee Schedule

Attachment to WTC Health Registry External Research Application

At this time, until a detailed cost analysis is completed, the only fees for external researchers are the cost of postage for the mailing of informational materials to registrants and the delivery fee cost for pickup by the U.S. Post Office.

This is a working policy and procedures and fee schedules may change in the future.

The World Trade Center Health Registry works foremost to protect the confidentiality of our registrants. Thus, if an external researcher's request to send informational materials about his/her study to WTCHR registrants is approved, the WTCHR program will send to the researcher a copy of the DOHMH non-endorsing cover letter and DOHMH envelopes. The researcher will prepare the informational packets, including the DOHMH cover letter, place these packets in the DOHMH envelopes, affix postage to the envelopes, seal the envelopes and send these packets to DOHMH. It is the responsibility of the researcher to insure that sufficient postage is attached to the envelopes.

Upon receipt of the envelopes, WTCHR staff will affix the appropriate mailing labels. Envelopes will then be picked up by the U.S. post office from the World Trade Center Health Registry office. The charge for this delivery fee from the U.S. post office will depend on the size of the mailout (see below). The researcher shall mail or deliver to the World Trade Center Health Registry a check made payable to the "Post Master" in advance of the mailing.

The charge for delivery of envelopes is as follows:

<u>Number of envelopes in mailing</u>	<u>Size of envelopes</u>	<u>U.S. Post Office delivery charge</u>
0-500	10" x 13"	free of charge
500-2000	10" x 13"	\$ 12.50
2001-4000	10" x 13"	\$ 25.00
4001-6000	10" x 13"	\$ 50.00
0-500	business letter-size	free of charge
500-4000	business letter-size	\$ 12.50
4001-8000	business letter-size	\$ 25.00
8001-12,000	business letter-size	\$ 50.00