

## **APPLICATION CHECKLIST**

- ☐ Application
- ☐ Brief Proposal (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)
- ☐ 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)

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

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

|                   |      |        |
|-------------------|------|--------|
| Telephone number: | Fax: | Email: |
|-------------------|------|--------|

(If there are no Co-PI's, enter "None".)

#### 4. Type of WTCHR Request:

### 5. Estimated Cost of Request, Funding Source and Level of Funding:

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## 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 hypotheses 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 WTC HR 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:**

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**2. Briefly describe your population of interest:**

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**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):

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

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

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

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**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:**

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## **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:**

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**2. Briefly describe your population of interest:**

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**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:**

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## **Fee Schedule**

### **Attachment to WTC Health Registry External Research Application**

At this time, until a detailed cost analysis is completed, the only fee for external researchers is the cost of postage for the mailing of informational materials to registrants.

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. Upon receipt, WTCHR staff will affix the appropriate mailing labels and deliver to the US post office for mailing. It is the responsibility of the researcher to ensure that sufficient postage is attached.