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List of Terms and Abbreviations

NYC DOHMH:	New York City Department of Health and Mental Hygiene
PTSD:	Post-traumatic stress disorder
Wave 1:	The WTCHR’s initial survey (2003-2004)
Wave 2:	The WTCHR’s second survey (2006-2008)
Wave 3:	The WTCHR’s third survey (20011-2012)
WTCHR:	World Trade Center Health Registry

Final Report Abstract:

Title: ***Extension of the World Trade Center Health Registry***.
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Background: The WTC Health Registry, the largest post-disaster exposure registry in U.S. history, was created to follow for 20+ years a diverse cohort of 71,437 directly affected people who performed rescue/recovery work or who lived, worked, attended school or were present in lower Manhattan on 9/11/01. Goals are to identify the long-term health effects of 9/11 and gaps in care; disseminate findings and recommendations to enrollees, others exposed and the scientific community; inform enrollees about 9/11-related services; and inform healthcare policy and disaster response planning. Specific aims during this 3-year project period included: (1) Maintain the Registry as a public health resource; (2) Expand knowledge about medium -term physical and mental health effects of the 9/11 disaster; and (3) Respond to health concerns and needs of enrollees.

Methods:
Maintenance activities included communications with enrollees to maximize valid contact information, address concerns, and keep them engaged and interested in future research; tracing to locate lost enrollees; outreach to boost survey response rates; and consultation with scientific, community and labor advisors.

Research activities included conducting priority epidemiological analyses using Wave 1 (2003-04) and Wave 2 (2006-08) survey data, including analyses to assess risk factors for the development or persistence of serious respiratory and mental health conditions over time; successfully conducting a Wave 3 (2011-12) adult survey (~43,000 (63%) participated) and launching a pediatric survey (ongoing) to ascertain cohort health status and healthcare needs 10 years after 9/11; initial cancer and mortality assessments; investigations of emerging health conditions, including respiratory health of survivors; and facilitating independent and collaborative 9/11-related external research by providing de-identified data and facilitating recruitment of enrollees.

Multiple record matches were conducted to link enrollee records to death records (e.g., NDI, NYC Vital Statistics, SSA) and 11 state cancer registries to assess mortality and cancer incidence 7-8 years after 9/11.

Communications activities included disseminating findings to enrollees, the public and policy makers via the 9/11 health info website, annual reports, newsletters, and presentations at scientific conferences (n=39) and other meetings (n=29); developing and disseminating pediatric clinical guidelines; referring eligible enrollees to WTC Centers of Excellence and smoking cessation programs; and developing online data tools for enrollees, the public and researchers.

Results: Registry publications and in-depth studies have been instrumental in informing 9/11-related health care policy for residents, area workers and rescue recovery workers. A total of 26 articles were published or submitted that reported on risk factors and health burden associated with a range of 9/11-related physical and mental health outcomes (e.g., cardiovascular disease, asthma, PTSD, sarcoidosis, birth outcomes, cancer, mortality, and co-occurring conditions) in the Registry population

and/or subgroups (e.g., responders, survivors, children, tower survivors, volunteers). Multiple external and collaborative studies have addressed priority topics including PTSD and respiratory health among adults and children's mental health. Two PhD and eight master's theses were completed based on analyses of Registry data. The Registry continues to be a valuable public health resource, and enrollees remained engaged with few withdrawals (1%) and persons lost to follow-up (0.35%).

Section I: Summary

A. Significant (key) findings

The Registry is a unique scientific resource for understanding the full scope and burden of the physical and mental health impact of 9/11, including cancer and mortality, and documenting 9/11-related healthcare needs. The Registry is the entity with the ability to prospectively follow the largest and most diverse cohort of persons directly exposed to the environmental effects of 9/11, including understudied groups such as lower Manhattan residents, office workers, and children.

The Registry has made a substantial contribution to the scientific literature on 9/11-related adverse health outcomes through the publication of 30 peer-reviewed manuscripts to-date. During the three year period of this cooperative agreement, the Registry has published 23 manuscripts and submitted an additional 3 manuscripts. The publications during this 3 year period span priority issues and conditions through 5-6 years post-9/11 based on our Wave 2 survey, including new onset asthma and PTSD among adult survivor and responder enrollees (nominated for the CDC Charles B. Shepard Science Award), gastroesophageal reflux symptoms, comorbid PTSD and respiratory symptoms, and childhood asthma, as well as a paper on the health benefits of respiratory protection among 9/11 responders (also nominated for the CDC Shepard Science Award). Other papers have focused on understudied groups such as rescue/recovery volunteers and Staten Island landfill and barge workers, findings from in-depth studies of birth outcomes of women pregnant on 9/11, and lung function of adults with persistent respiratory symptoms. Other papers addressed potential emerging conditions (cancer, mortality, heart disease, sarcoidosis, skin conditions) among rescue/recovery workers, residents, office workers and children. The initial mortality study and a review of mid-term effects were included in the special Sept. 2011 volume of The Lancet on 9/11 health outcomes and the 10th anniversary perspective on 9/11-related health consequence was published in JAMA in Sept. 2011. The first manuscript on cancer was submitted to a peer-reviewed journal.

The Registry also facilitates collaborative and independent studies by U.S. and international academic researchers by providing de-identified data and cost-efficient access to enrollee subgroups for recruitment. External studies approved to-date range from basic research (*e.g.*, using functional MRI to understand the brain's response to terrorism), to a clinical trial of combined treatments for PTSD among 9/11 survivors, to investigations of the impact of PTSD among responders on their children. The Registry has also initiated collaborations with NIOSH-funded WTC Centers of Excellence in NYC related to cancer assessment, investigations of potentially emerging health conditions, and lung function of symptomatic residents and office workers. Notably, Registry findings complement findings from the WTC Health Program and provide a more comprehensive understanding of 9/11 health impacts. In addition, the Registry has a strong commitment to public health training. In the past three years, two PhD theses and eight master's level theses have been completed by staff and interns using Registry data.

The high degree of enrollee participation in Registry activities to date bodes well for the long-term viability of the Registry as a resource for researchers, policy makers and the public. More than 63% of all adult enrollees participated in the 2011-12 Wave 3 survey (including nearly 78% of Wave 2 participants); similar response rates were obtained for Registry in-depth studies. Additionally, to date thousands of enrollees have participated in approved external studies, enrollees have sent over 46,000 updates to contact information, and few have withdrawn (~1%) or are currently lost to follow-up (~0.35%).

The Registry has adopted broader research paradigms in several ways. First, we have completed early cancer and mortality incidence studies that employed both internal and external comparisons; for within-cohort comparisons, we developed a graded exposure metric to assess the association between the intensity of 9/11 exposure and relevant outcomes. Secondly, we collaborated with WTC Centers of Excellence for responders (FDNY/Mt. Sinai) on a study of a potential emerging condition among enrollees (sarcoidosis) and demonstrated we could address potential overlap of cases across cohorts. Thirdly, we examined co-morbid health conditions to include comorbidity of physical and mental health outcomes, rather than co-morbid mental health conditions or comorbid physical health conditions alone.

New approaches include the use of personalized outreach and staff trained in motivational interviewing techniques in our treatment referral project. This approach has proven to be more effective than generalized outreach in encouraging and facilitating first time appointments by symptomatic enrollees at the WTCHP Centers of Excellence. The Registry also introduced several refinements and new applications of methodologies, instrumentation or interventions. We implemented a new application of existing instrumentation, impedance oscillometry, to understand distal lung function post-disaster in our study of residents and area workers with persistent lower respiratory symptoms. We also developed refined exposure metrics based on self-reported 9/11-exposures (used in the respiratory, cancer and mortality studies) and employed a novel combination of self-reported mental health diagnosis and symptoms in assessing unmet mental health care needs. Consistent with our approach of operating a comprehensive Registry, we conducted a smoking cessation project customized for current smoker enrollees and their household members.

B. Translation of findings

The Registry has also informed clinical practice by publishing studies on a range of health outcomes, emerging conditions and risk factors across diverse exposed populations, as well as unmet health care needs, and barriers to 9/11-related healthcare. Furthermore, we collaborated with the clinical WTC Centers of Excellence and NYCDOHMH experts to develop clinical guidelines for physicians caring for adults and children exposed to 9/11, that emphasized asking patients questions about their 9/11-exposures and assessing for both 9/11-related physical (e.g., aero-digestive conditions) and mental health conditions; distributed these guidelines to all NYC providers and shared them with NIOSH.

The Registry regularly translates its findings into public documents and recommendations for health care providers. Registry findings are widely disseminated through NYC DOHMH's 9/11HealthInfo website, e-newsletters, press releases, an annual report, and the annual reports of the NYC WTC Medical Working Group. We also published findings describing the creation of the Registry and lessons learned.

Registry research has implications for improved worker safety. Recommendations from Registry published findings include: the importance of respiratory protection for rescue/recovery workers and volunteers, the increased vulnerability of uniformed and volunteer workers assigned to rescue/recovery tasks without sufficient training and/or exposed to novel hazardous environments, and the increased vulnerability of already stressed populations (e.g., lower socioeconomic status or educational level, undocumented workers) to traumatic events.

C. Outcomes/Impact

Registry research has informed healthcare policy. Our published estimates of the burden of 9/11 health impacts in affected populations and information on unmet care needs have been shared with city and federal officials, justifying the need for extended healthcare services for survivors and responders via the WTC Health Program established under the Zadroga 9/11 Health and Compensation Act of 2010.

Registry collaborative and independent external published research (facilitated by the Registry) has provided recommendations for: improvements to evacuations from high rise buildings, reducing the impact PTSD among first responders has on their children, and identification of organizational and behavioral barriers to rapid and efficient evacuation of buildings in a disaster.

Section 2: Scientific Report

This progress report covers the period April 30, 2009 – July 8, 2012. It is organized by the Registry's three original aims.

A. Background

Brief description of the 9/11 disaster

The events of Sept. 11, 2001 in New York City (NYC) were unprecedented. Two airliners crashed into the World Trade Center (WTC) twin towers, resulting in large explosions and fires. The towers collapsed within two hours, releasing dust clouds, smoke and debris. Four buildings collapsed later and 32 others had moderate to major damage. Nearly 2,800 people died, including more than 2,200 civilians, 343 firefighters, and 60 police officers. Hundreds of thousands of people were exposed to environmental contaminants and witnessed traumatic events. Tens of thousands of lower Manhattan building occupants, residents and school children were evacuated and had their lives and livelihoods disrupted for months to years afterward. An estimated 91,000 responders, volunteers, construction contractors and others arrived to work at or nearby the WTC site on 9/11 or in the days and months thereafter, shifting from rescue to recovery work. The effort involved city, state and federal agency employees, contracted workers and volunteers from all 50 states.

Registry rationale, creation and ATSDR collaboration

Shortly after the 9/11 attacks, the NYC Department of Health and Mental Hygiene (NYCDOHMH) proposed to the Agency for Toxic Substances and Disease Registry (ATSDR) the formation of a registry of 9/11-exposed persons in order to track the health impact. ATSDR secured funding from FEMA to establish the World Trade Center Health Registry in July 2002 and partnered with NYCDOHMH to implement it through a cooperative agreement over the six-year period ending April 30, 2009 (with support from ATSDR, FEMA, EPA and CDC's National Center for Environmental Health). ATSDR scientists and managers had substantial programmatic involvement in the Registry's design, recruitment and outreach methods, questionnaire content, data collection and analysis, and manuscript preparation. As an ATSDR assignee, Dr. Robert Brackbill served as founding principal investigator (2002-06) and is now with DOHMH as a senior Registry researcher.

The Registry was established as an essential public health resource with the following objectives: to identify the long-term physical and mental health effects of the WTC disaster among people most directly exposed; document the duration and severity of health impacts; disseminate findings and recommendations to enrollees, others exposed, the public, and the scientific community; share information about 9/11-related resources and services; and inform response planning for future disasters. This cohort study was designed to track enrollee health for at least 20 years post-9/11. IRB approvals were obtained in 2002-03 from CDC and NYCDOHMH, and a Federal Certificate of Confidentiality was obtained and renewed. During Sept. 2003 to Nov. 2004, 71,437 persons voluntarily enrolled and completed the Registry's Wave 1 interview.

Approach

Our approach to operating a long-term registry is to maintain and expand a comprehensive Registry that (a) addresses priority research issues; (b) collaborates with external researchers and the WTCHP; and (c) keeps enrollees engaged and responds to their health needs and concerns through targeted treatment referral and health promotion efforts and other efforts to address identified health issues (e.g., facilitating PTSD treatment effectiveness studies). Our approach includes (a) investing in staff training, development, and retention, including encouraging staff to use Registry data to address priority Registry research topics for their masters and doctoral theses; (b) involving preventive medicine residents in priority Registry projects; and (c) maintaining academic links for recruiting strong interns and college aides to work part-time at the Registry, including MPH students seeking to do Registry-related masters projects. This approach has resulted in the successful development and retention of staff and the continuity of working relationships with NIOSH program and administrative staff, external researchers, and the WTC Centers of Excellence. This has enabled us to exceed the number of planned publications during the past 3-years. The Registry's established working relationships with enrollees, advisors, stakeholders, NIOSH, and the WTCHP will also enable us to attain the four specific aims in an efficient manner and continue to serve as a model for future post-disaster registries.

Description of the World Trade Center Health Registry

Eligibility Groups: The selection of eligibility groups took into account proximity by time and place to the WTC attacks and likelihood of acute exposure to the immediate dust cloud that resulted from the collapse of the towers and ongoing exposures to dust, smoke and fumes in the vicinity of the WTC site. Four eligibility groups were created to include persons most likely to have had direct exposure on 9/11 and its aftermath:

1. Persons present in lower Manhattan south of Chambers St. on the morning of 9/11, including occupants of damaged/destroyed buildings and other nearby buildings (area workers), passers-by, and people in transit.
2. Rescue/Recovery Workers and Volunteers at the WTC site in lower Manhattan, at the Recovery Operations on Staten Island, or on barges transporting debris between the sites for at least one shift anytime from September 11, 2001 through June 30, 2002
3. Residents whose primary residence was south of Canal Street in lower Manhattan on 9/11, and
4. Students and Staff of schools (grades pre-K through 12) south of Canal Street on 9/11

Except for #1, persons did not have to be present in lower Manhattan on the morning of 9/11 to be eligible.

Sample Building, Outreach and Recruitment: Enumerating the population to be sampled and recruitment was an intensive process that lasted more than a year. Community outreach, list-building (collection of lists of potentially eligible persons) and self-identification (pre-registration via a widely marketed toll-free telephone number or a Registry web site) were used to build a robust sample. Approximately, 2,200 entities (e.g., employers, governmental agencies, schools, unions) were contacted for lists of names and contact information of potentially eligible persons. Lists were also obtained from publicly available sources (e.g., Genesys lists for lower Manhattan residents). A total of 232 lists were obtained, including for responders/volunteers (144 lists), building occupants (76 lists), students/school staff (9 lists), and residents (3 lists). The nearly 198,000 potential enrollees identified (135,450 from lists, 62,502 by self-identification) were contacted if possible for an interview.

Coordinated advertising and media campaigns were conducted (via newspaper/radio/bus/subway ads) throughout the enrollment period. Outreach was also conducted to create awareness, motivate eligible persons to self-identify, and reach hard-to-locate persons (e.g., undocumented workers, lower Manhattan visitors). Outreach materials in English, Spanish and Chinese provided the toll-free telephone number and pre-registration web site. Brochures were placed in over 1,000 lower Manhattan businesses. Informational tables were staffed at schools, residential buildings, and numerous public events in lower Manhattan, and presentations were made to community groups, schools, downtown businesses, and work sites.

Wave 1 Survey: Of the 71,437 baseline interviews conducted between Sept. 2003 and Nov. 2004, 95% (n=67,527) were completed using computer-assisted telephone interviewing (CATI) and 5% (n=3,910) were completed using computer-assisted personal interviewing (CAPI). The interview, lasting about 30 minutes, was administered in English (95.2%), Spanish (1.9%), Cantonese (1.5%), and Mandarin (1.0%). A translation service was used for other languages (n=315). Parents/guardians served as proxies for children under 18 years at interview (n=2,635). Proxy interviews were conducted for adults who were deceased after 9/11 (n=157) or seriously mentally or physically ill or otherwise unable to respond (n=308). A fully documented data file user's manual for researcher use includes a description of survey design, testing, and implementation, a transcript of the CATI script used in the interviews, and a codebook-style listing of variable frequencies. The survey and manual are available to the public on the Registry's webpage.

The interview included: (a) informed consent; (b) eligibility determination; (c) demographics; (d) contact information for the enrollee and up to 3 relatives and friends; (e) exposure questions for all enrollees (types of 9/11 injuries; presence, duration and location in the dust cloud, witnessing horrific events); (f) specific exposure questions by eligibility group (e.g., home evacuation and date of return); (g) building evacuation and date of return to the workplace; location, type, and dates of rescue/recovery work); (h) physical health symptoms and conditions before and after 9/11; and (i) mental health symptoms in the 30 days prior to the interview. Physical health outcomes included new or worsening respiratory symptoms and non-respiratory symptoms after 9/11 (e.g., shortness of breath, hearing problems, severe headaches, heartburn,/indigestion/reflux, and skin rash); and physician-diagnosed conditions after 9/11 (e.g., asthma, emphysema, hypertension, coronary heart disease, angina, heart attack, diabetes, stroke, and cancer). Symptom questions were similar to those used in the Behavioral Risk Factor Surveillance System.

The adult interview assessed non-specific psychological distress using the Kessler-6 scale (K-6), a psychometrically validated, epidemiologic screening measure used in the National Health Interview Survey since 1997 and probable current PTSD using the PTSD-Checklist Civilian Version (PCL), a standardized event specific 17-item symptom scale corresponding to the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, DSM-IV criteria. Proxy interviews with parents/guardians included an 8-item scale derived from Hoven *et al.* to assess possible posttraumatic stress symptoms among children.

Wave 2 Survey: Separate questionnaires for adults, parents of children and adolescents, and adolescents were developed and tested. The Wave 2 survey of all enrollees had the following objectives:

- Measure current health status (5-6 years after 9/11) and assess possible relationship to 9/11 exposures
- Clarify timing of onset of asthma and other illnesses and assess unmet healthcare needs
- Assess persistence and resolution of health symptoms and conditions reported at Wave 1
- Obtain or clarify exposure data (e.g. dust cloud, home/office condition; respirator/mask use)
- Obtain information on additional covariates (e.g., social support and bereavement)

The adult Wave 2 survey was administered in English, Spanish, and Chinese between Nov. 2006 and Jan. 2008 and had a common core of questions for all adults (n=68,959 excluding known deaths and withdrawals but including children who became adults prior to Wave 2), and three exposure-specific modules (available to the public on-line at the Registry's website). Module A elicited from lower Manhattan residents details of the condition of their homes post-9/11 and subsequent clean-up efforts. Module B asked occupants of damaged and destroyed buildings about their evacuation experiences. Module C asked workers who performed rescue/recovery work on the WTC debris pile about respiratory protection training, type and use.

Wave 2 for adults had three survey modes: web, paper (mail), and CATI. Beginning in Nov. 2006, enrollees with email addresses (63%) received an email invitation to access the online survey (English only). Language-appropriate paper surveys were mailed to the remaining adult registrants. Following multiple mail and email reminders, the Registry's vendor began making calls in Sept. 2007 to the

26,500 non-respondents to offer telephone interviews. More frequent call attempts were made to lower responding groups (household income < $35,000, age 18-24 years, non-white, residents age > 65 years, and Spanish and Chinese speakers). A total of 46,701 (67.7% response rate) adult surveys were completed by mail (n=21,616), web (n=19,431) and phone (n=5,654). The Wave 2 data set was merged with Wave 1 data for use in generating Registry papers.

The pediatric Wave 2 survey was conducted from June 2007 through Dec. 2008. The child version was sent to the parents/guardians of enrollees aged 5 to 10 years. The version for adolescents aged 11 to 17 years included a survey booklet for parents/guardians and a separate booklet for adolescents. The Wave 2 survey included questions for parents regarding household composition and questions for adolescents about their mental health, behavior at home and school, interactions with adults and other children, as well as smoking and other risk factors. The survey employed only paper surveys that were mailed to 2,017 parents/guardians of child enrollees in the summer of 2007. Through Dec. 2008, multiple rounds of reminder postcards and three additional rounds of surveys were mailed to non-respondents. To boost response, 4 rounds of reminder phone calls were made and two rounds of door-to-door outreach were targeted to non-respondents in NYC and New Jersey. A total of 1,012 pediatric surveys were completed for an overall response rate of 50.2%.

B. Specific Aims

AIM 1: Maintain the Registry as a valuable public health resource

This aim entails sustaining critical Registry infrastructure and communications for maximizing enrollee participation and ensuring the utility and longevity of the Registry.

- ***Aim 1a*****:** Maximize the number of enrollees with valid, updated contact information through ongoing communications and tracing activities to locate enrollees lost to follow-up
- ***Aim 1b****:* Maintain timely, accurate and professional communications and feedback with enrollees to address concerns and keep them engaged and interested in participating in future research
- ***Aim 1c*****:** Conduct outreach to boost response to Registry studies

AIM 2: Expand knowledge about the long-term health effects of the 9/11 disaster by continuing the WTCHR research program

- ***Aim 2a:*** Describe the health of enrollees and quantify risk factors for adverse health conditions by conducting priority analyses based on the 2003-04 and 2006-07 surveys
- ***Aim 2b*****:** Develop and conduct a second follow-up survey (“Wave 3”) to ascertain the health status of the cohort 10 years after 9/11
- ***Aim 2c*****:** Complete initial cancer and mortality assessments
- ***Aim 2d:*** Identify and investigate potential emerging health conditions
- ***Aim 2e*****:** Facilitate independent and collaborative research by sharing data and resources with WTC Centers of Excellence and qualified academic researchers

AIM 3: Conduct community activities to respond to the health concerns and specific needs of enrollees and others exposed to 9/11

The Registry believes it has a public health obligation to respond to both physical and mental health concerns and needs of enrollees and others exposed to 9/11. Since the WTCHR was not designed to provide direct healthcare services, this aim will be achieved by expanding the following research translation components of the Registry

- ***Aim 3a*****:** Disseminate Registry findings and recommendations to enrollees, the public and policy makers

- ***Aim 3b*:** Inform enrollees of 9/11-related services, resources, and health promotion programs
- ***Aim 3c:*** Develop and provide Registry data resources for, and respond to inquiries from, for enrollees and the public
- ***Aim 3d*:** Develop and disseminate updated 9/11-related treatment guidelines for physicians and other providers
- ***Aim 3e:*** Offer healthcare referrals to enrollees with identified healthcare needs

C. Methodology

AIM 1: Maintain the Registry as a valuable public health resource

NYCDOHMH developed and implemented a Registry maintenance plan based on recommendations from investigators at other large and successful health registries and longitudinal cohort studies (e.g., sending an Annual card to all enrollees). Because the Registry's longevity depends on ongoing communications with enrollees, tremendous efforts have been made to address their concerns, and to keep them engaged and interested in participating in future research and providing us with their up-to-date contact information. Many of these activities are described in this Aim while others are described under Aim 3.

Aim 1a: Maximize the number of enrollees with valid, updated contact information through ongoing communications and tracing activities to locate enrollees lost to follow-up

Panel Maintenance (PM) staff lead the effort to maintain updated contact information for Registry enrollees.

Updated Contact Information: Enrollees were provided with several channels to contact PM staff to obtain information, ask questions, and update contact information. Multiple communications were sent to enrollees. These communications intensified in the year prior to the Wave 3 survey launch. An update contact information page, accessible via the Registry webpage on the NYC 9/11HealthInfo website, permits enrollees, after a brief registration and verification process, to enter their updated contact information including contact information for their secondary contacts (e.g., family and friends).

Enrollee Tracing: Relying on enrollees to actively contact the Registry with updated contact information is insufficient for maintaining the accuracy of contact information; hence the Registry puts substantial effort into tracing. Registry and RTI staff conducted periodic tracing of groups, or "batches", of enrollees as well as individual-level ("intensive") tracing to obtain the most updated contact information. Enrollees enter the Tracing Queue when they have at least one missing or undeliverable/unreachable piece of contact information. Some enrollees many have a deliverable mailing address but are missing a valid home phone number, while others have no valid contact information and are classified as "currently lost". The tracing queue is fluid as cases are resolved and new cases enter the queue (i.e., with a newly undeliverable mailing address).

Integrate updates into the Registry database: There are two general sources of updates to contact information, (1) direct updates from enrollees or a relative, and (2) indirect updates through secondary sources. The Registry uses two tools to capture changes or corrections to enrollees' contact, demographic and preference information: (1) rTools – a Registry IT custom-designed computer interface application that Panel Maintenance (PM) staff use, and (2) Batch Processing – a process where updates to a group of enrollees' information are uploaded to the database at one-time by the Registry's IT/Systems staff or the PM Head.

In addition to contact information updates, PM staff record enrollee preferences (e.g., preferred no contact via email, or preferred email contact), language preference, survey completion dates, demographic corrections, and requests to withdraw (from the current survey, special project activities or the Registry). PM staff also record change in status for deceased enrollees identified via record matches with NYC Vital Records, the National Death Index (NDI), and the Social Security Administration (SSA), to exclude these enrollees from future communications. All changes and updates undergo a thorough quality control review before they are permanently uploaded. Previous information is retained in case it is needed in the future.

Current Status of Enrollees: Enrollee status was assessed periodically, in part to measure the effectiveness of communication and tracing activities at increasing the number of active enrollees and reducing the number of currently lost and presumed active enrollees. All enrollees were assigned to one of the following categories: deceased, withdrawn (from all future Registry activities), currently lost (no valid contact information), active (completed the Wave 2 survey or communicated with the Registry during the past ~ five years) or presumed active (all others).

Confidentiality and Data Security: We continued to strengthen protocols to maintain the integrity, confidentiality and security of the database and to ensure confidential communications with enrollees, including:

- All communications to >1 enrollee are approved by the Registry Director and Deputy Director
- Confidentiality agreements were signed by all staff/vendors using identifiable Registry data
- Transmissions of confidential data outside the NYCDOHMH network were encrypted
- The Registry database was stored behind the NYCDOHMH's IT network and firewall.
- The agency's Chiefs of Information, Confidentiality, and Security were informed of data projects and the latter inspected the Wave 3 survey vendor call center and security protocols before the Wave 3 launch.
- Access to confidential data was limited on a need to know basis, and IT staff monitored access

Aim 1b: Maintain timely, accurate and professional communications and feedback with enrollees to address concerns and keep them engaged and interested in participating in future research

All staff members are trained to respond in an appropriate, timely and professional manner in communications with the public and enrollees and to confirm contact information during every contact with an enrollee. Staff and vendors have been trained to appropriately respond to distressed enrollees and have access to NYCDOHMH's mental health medical director. All enrollee communications generally included: a reminder how to provide updated contact information, gratitude for their continued participation, and a reminder that their email address provides an environmentally-friendly way to communicate. All key communications materials were available in English, Chinese and Spanish, and multilingual Spanish, Cantonese and Mandarin speaking staff were available to speak with enrollees.

Respond to incoming communications: PM staff receive incoming communications daily, Monday-Friday from 9am-5pm, and typically reply within one business day.

Provide regular outreach and feedback: PM staff contacted individual enrollees via telephone, email or mail to obtain up-to-date contact information, resolve discordant demographic information, invite enrollees to participate in a special study or survey, or to respond to enrollee inquires. Senior medical staff responds to any medical concerns. In addition, the Registry's *Tobacco Cessation Project* and the *9/11 Treatment Referral Program* contacted individual enrollees to offer tobacco cessation services and referrals for 9/11-related treatment (see Aim 3e below).

Aim 1c: Conduct outreach to boost response to Registry studies

Registry staff conducted numerous outreach activities to enhance response rates to the Registry's Wave 3 adult and pediatric surveys and the Staten Island and Barge Workers Survey. Key components of outreach included media outreach, reminder telephone calls, community presentations, outreach to residential buildings in Lower Manhattan, and door-to-door outreach to individual adult enrollees or to the parents/guardians of adolescent enrollees.

Media outreach: As a key component to outreach, we implemented a Wave 3 media strategy to promote Wave 3 survey participation.

Reminder telephone calls: Outreach activities included two rounds of automated Wave 3 reminder calls conducted by Global Strategies Group (GSG), a NYC DOHMH communications vendor, first to adult enrollees and later to parents/guardians of pediatric enrollees who had not yet completed a Wave 3 survey.

Community presentations and outreach to residential buildings in Lower Manhattan: To boost response to the Wave 3 Adult survey, Registry staff set up tables in building lobbies and conducted community presentations in lower Manhattan because downtown residents had lower response rates compared to Responders. To boost response to the pediatric survey, the Registry also conducted community presentations where we promoted the importance of the survey.

Door-to-door outreach: Wave 3 Adult survey: In the winter of 2012, intensive door-to-door outreach was successfully conducted by English, Spanish and Chinese (Mandarin, Cantonese) speaking staff teams who either spoke directly with enrollees and provided surveys upon request, or slipped language-specific survey reminder flyers under their doors. Other DOHMH staff assisted in this effort with financial support from the Division of Epidemiology.

Door-to-door outreach: Wave 3 Pediatric survey: The Registry successfully conducted similar door-to-door outreach to parents/guardians of enrollees who had not yet responded to the Wave 3 pediatric survey. Intensive door-to-door outreach was conducted during weekday evening hours and on the weekend by English, Spanish and Chinese (Mandarin, Cantonese) speaking staff teams who either spoke directly with parents/guardians and provided surveys upon request, or slipped language-specific survey reminder flyers under their doors.

To further enhance response rates to the Pediatric survey, the Registry twice extended the deadline for survey submissions, and added an incentive of a $10 Barnes and Nobles gift card as a thank you to adolescent enrollees who participated in the survey.

AIM 2: Expand knowledge about the long-term health effects of the 9/11 disaster by continuing the WTCHR research program

The Registry's research plan for this three year cooperative agreement (2009-2012) directly addressed this aim and consisted of the five separate aims (2a-2e) as described in further detail below.

Aim 2a: Describe the health of enrollees and quantify risk factors for adverse health conditions by conducting priority analyses based on the 2003-04 and 2006-07 surveys

The initial plan for Registry Year 01-03 publications was to report on a wide variety of physical illnesses: asthma and other respiratory conditions, emerging conditions, birth outcomes, cancer and mortality. The research plan also included PTSD and other mental health problems and proposed to take into account policy issues such as access to health care, unmet health needs, and use of protective equipment and worker training.

Our initial plan proposed that NYC DOHMH would complete and submit for publication a wide range of analyses using data from the Wave 1 (2003-4) and Wave 2 (2006-7) surveys, including analyses that had already been underway at the beginning of the three year time period as well as initiate new analyses to link 9/11 exposures and other risk factors with development or persistence of serious conditions over time, characterize the co-morbidity of physical and mental illnesses, and understand treatment seeking patterns. The plan proposed to complete and submit up to 16-19 manuscripts during the 3-year time period. Within this group of manuscripts, we proposed to cover all Registry populations – rescue/recovery workers and volunteers; lower Manhattan residents and workers; passersby in lower Manhattan on 9/11, and children – diverse populations that experienced a wide range of exposures and health outcomes.

Aim 2b: Develop and conduct a second follow-up survey ("Wave 3") to ascertain the health status of the cohort 10 years after 9/11

Adult Wave 3 Survey (2011-12): The Wave 3 survey of all adult enrollees had the following objectives:

- Assessing health status of enrollees 10 years after 9/11, including the emergence and persistence of adverse physical and mental health conditions and symptoms, especially asthma, other respiratory conditions, cancer, depression and PTSD
- Assessing 9/11-related health care utilization and unmet needs and measuring covariates and confounders needed for data analysis
- Measuring a range of outcomes and ancillary measures (e.g., quality of life, social support, health)

The adult survey was administered in English, Spanish, and Chinese between June 2011 and March 2012. It had a common questionnaire for all eligible adults (n=68,378 excluding known deaths and withdrawals but including child enrollees who reached 18 years before Wave 3). Some questions from Wave 2 were dropped, others were retained and new questions were added.

Wave 3 was organized around the following data themes:

1. Current health status of enrollees (physical and mental health)
    - Symptoms and conditions, including for the first time depression and anxiety scales
    - Functioning and disability
    - Health care needs and access
    - Past and current medical needs, medical encounters, hospitalization
    - Barriers to health care access and utilization of dedicated 9/11 programs
2. Supporting variables (covariates and confounders that may help explain observed illness patterns and relationships with 9/11 exposures)
    - Socio-demographic variables
    - Anthropometric variables (e.g., height and weight; weight gain/loss after 9/11)
    - Risk factors other than 9/11 (e.g., history of traumatic events, smoking, alcohol)
    - Social support, quality of life, functional status, insurance status

Similar to Wave 2, the adult Wave 3 survey gathered data via three modes: web, paper (mail), and computer assisted telephone interviews (CATI). Beginning in June 2011, enrollees with email addresses received a personalized email invitation to access the online survey (English only). Email invitations were released in batches through end of July 2011 to ensure maximum server capacity was not reached on a given day. Language-appropriate personalized paper surveys were mailed to the remaining adult enrollees in mid-July 2011.

Following multiple postcard (up to 5) and email reminders (up to 14) and up to three paper survey mailings, the Registry's vendor (RTI International) began calls in Sept. 2011 to offer CATI to survey non-responders. Cases were rolled out throughout the CATI period. Telephone interviewing efforts were focused on enrollees who had completed the Wave 2 survey to maximize the number of enrollees with longitudinal data at three time points. Enrollees who had only completed Wave 1 were added to the CATI sample near the end of Wave 3 data collection. During the CATI phase, enrollees could still choose to fill out their surveys via web or mail.

Mode experiment: To help isolate the effect of mode on Wave 3 responses, an experiment was conducted. Three similar groups of ~400 enrollees were initially assigned to only one mode: web, mail, or CATI. These groups were stratified such that each group had ~1/4th of its cases in each of the following Wave 2 categories: web responders, mail responders, CATI responders, and non-responders.

Pediatric Wave 3 survey (in progress): At the time of survey launch in Nov. 2011, all child enrollees were at least 10 years old. The Registry implemented a self-report survey for all 10-17 year olds (N=1,204), with separate surveys for their parents/guardians. We requested that the child surveys be filled out separately to maintain privacy. For the first time, we offered parents and adolescents a web-based survey in addition to a paper survey to make the survey more user-friendly and cost-efficient. Past research on internet-based surveys in children aged 10-17 indicated that we could expect potentially higher response rates and more complete data. Questionnaire content was guided by similar research objectives to those noted above for the adult survey. The pediatric survey excluded Wave 2 questions related to 9/11 exposures and school experiences, but retained other Wave 2 questions. The survey had new questions on more common physical and mental health conditions and symptoms and new topics such as quality of life, health insurance coverage, and hospitalizations.

Similar to the adult Wave 3 survey, multiple rounds of paper surveys (up to 5), postcard reminders (up to 11) and email reminders (up to 10) were sent to non-responders, reminder phone calls and door-to-door visits were made to non-responders to boost response. Data collection will continue through at least October 2012. To enhance response rate, the survey deadline was extended twice and a $10 gift card was added an incentive to thank adolescents for completing their survey.

Aim 2c: Complete initial cancer and mortality assessments

Background: The Registry was originally designed to serve as a platform for mortality and cancer incidence studies, key components of Aim 2. Much public concern has focused on potential risks of cancer and premature death due to WTC exposures.

Funding for cancer and mortality assessment was initially established in Sept. 2006 by a Mayoral 9/11 Initiative to NYCDOHMH using NYC City Tax Levy funds. Surveillance activities for cancer and mortality under this 2006-2010 initiative included: conducting matches with death records, cancer registries and hospitalization data in order to identify possible increases; beginning to examine the relationships between WTC-related exposures (e.g., the degree of reported dust cloud exposure or duration of work at the disaster site) and excess overall or cause-specific morbidity or mortality; beginning to assess whether a dose-dependent relationship exists between the WTC-related exposures (or other risk factors) and morbidity and mortality; and developing a methodology for cancer and death identification that will enable routine assessments of morbidity and mortality in the future. Under this Mayoral 9/11 Initiative, the Registry established mechanisms for routinely matching Registry records with NYCDOHMH Vital Statistics death files, the National Death Index (NDI), the Social Security Administration's (SSA) Death Master File and New York State (NYS) and 10 other state cancer registries.

Beginning in Year 2, this cooperative agreement has provided support for all of the Registry's cancer and mortality assessment activities.

Cancer Assessment: We have maintained an active status with each of the 11 state cancer registries for our cancer surveillance through annual IRB renewals. Together these 11 states represent the current residence for 96% of Registry enrollees. We conducted two rounds of matches to these 11 state cancer registries and obtained cancer records through 2008. The Registry's first systematic examination of cancer incidence was conducted among enrollees who were NYS residents on 9/11. This study used external (standardized incidence ratio, SIR) and internal comparisons (Cox proportional hazard modeling). Cases of first primary invasive cancer identified through these matches for the study population were used. Expected numbers were calculated using life table methods and both New York City and New York State cancer rates and Standardized Incidence Rations (SIR) for all major cancers.

Cancer Validation: Registry medical and research staff conducted medical record review and/or clinical confirmation of self-reported cancers for those enrollees who reported cancer to the Registry but who did not match to a state cancer registry.

Mortality Assessment: We conducted multiple matches to several sources of mortality records, and obtained mortality records through 2008 from NDI, through 2011 from SSA, and through 2009 from NYC Vital Statistics.

2010 Cancer and Mortality Methods Workshop and Follow-up: The Registry assisted in the planning and attended this workshop on June 21-22, 2010. Nationally recognized experts in cancer epidemiology, environmental health and biostatistics from around the U.S. attended and provided advice on how best to proceed with cancer studies of 9/11-exposed populations. The meeting addressed general methodological issues as well as a list of specific questions. The experts made recommendations concerning the analytic methods that researchers should consider when analyzing the post-9/11 cancer diagnoses that have been confirmed among the various WTC cohorts including: (1) Use of internal comparisons is expected to be more meaningful scientifically than external comparisons to other groups because of the difficulty in identifying comparable, non-exposed populations and the differences in exposure metrics between research groups, (2) Researchers should consider conducting formal analyses no more frequently than every five years because of the relatively small size of the cohort. However, during the interim, monitoring and tracking of the data can continue so that researchers can detect and share developments of interest, and (3) WTC Centers of Excellence and the Registry should consult with each other on an ongoing basis about cancer analyses within their cohorts and coordinate reporting of data and/or research. Full recommendations were published in the Mayor's Medical Working Group 2010 Annual Report available at the NYCDOHMH 9/11 health info website.

Subsequent to the Methods Workshop, the Registry participated in a series of meetings with the WTC Centers of Excellence to discuss development of a common exposure matrix, cancer definitions and resolving cancer ascertainment. In April 2012, the Registry hosted a Research Roundtable to discuss our recent mortality and cancer findings and future possible analyses. Michael Thun, MD, a member of the Methods Workshop expert panel from the American Cancer Society, attended and presented.

Aim 2d: Identify and investigate potential emerging health conditions

The Registry has investigated emerging health conditions based on results of the Wave 2 survey (including GERS), published reports from other cohorts (sarcoidosis, skin rash), and results of our mortality study (heart disease). In addition, the Registry has performed in-depth investigations of specific cancer types reported by clinicians from the WTCHP (e.g., hematological malignancies) and reported by medical directors of private companies involved in WTC cleanup (e.g., thyroid cancer).

In May 2010, we obtained approval from the NYS DOH to conduct a data match between the Registry and the Statewide Planning and Research Cooperative System (SPARCS) administrative hospital database. The current agreement will enable the Registry to obtain linked SPARCS data on enrollee inpatient hospitalizations and ambulatory procedures (from 1996-2013) and on emergency department visits (from 2005-13) for future studies. The Registry's first installment of SPARCS data, which contains inpatient hospitalization data from 2000-2010, was received in November 2011. The data match performed by NYS DOH resulted in many potential matches which the Registry will evaluate in Years 04-07.

Aim 2e: Facilitate independent and collaborative research by sharing data and resources with WTC Centers of Excellence and qualified academic researchers

The Registry has had multiple research collaborations with the WTC Centers of Excellence that comprise the WTCHP and other external researchers including collaborative in-depth studies, analyses of Registry survey data, and studies in which the Registry facilitated enrollee recruitment on behalf of external researchers.

External Research Program: The external research program is a mechanism to leverage the expertise and resources of outside investigators and institutions to accomplish research goals beyond the capacity of Registry personnel and facilities. Potential investigators submit a research proposal for peer review by the Registry's External Research Committee comprised of Registry staff and advisors. A study can be an independent analysis of Registry data or a collaborative analysis with Registry researchers. The Registry can share de-identified data and/or facilitate enrollment in external studies by offering selected enrollees the opportunity to participate in a new study which may involve new interviews or clinical examinations carried out by external investigators with appropriate credentials.

See *Section 2L: Materials available for other researchers* for a summary of available resources for external and collaborative researchers.

AIM 3: Conduct community activities to respond to the health concerns and specific needs of enrollees and others exposed to 9/11

The Registry believes it has a public health obligation to respond to both physical and mental health concerns and needs of enrollees and others exposed to 9/11. Since the WTCHR was not designed to provide direct healthcare services, this aim will be achieved by expanding the following research translation components of the Registry.

Aim 3a: Disseminate Registry findings and recommendations to enrollees, the public and policy makers

Registry Advisory Committees: The Registry met regularly with our scientific advisory committee (SAC), community advisory board (CAB), and labor advisory committee (LAC) to provide updates on Registry findings and solicit feedback and advice. The Registry continued to reach out to communities directly affected by 9/11 (e.g., the community boards of lower Manhattan) to request that these groups send representatives to advisory meetings. Additionally, a representative from each advisory committee serves on the Registry's External Review Committee that considers external research proposals

All three committees were involved in the development of the adult and pediatric Wave 3 survey, each providing multiple rounds of feedback on the questionnaires. The Registry also established 5 working groups consisting of scientific, labor and community advisors and outside experts, each focused on a particular Wave 3 survey topic: physical health, mental health, health care needs, maximizing response rate, and pediatric health issues. During data collection, our advisors provided additional ideas for boosting survey response.

SAC members, many of whom are involved in 9/11-related research, represent a variety of scientific disciplines including epidemiology, clinical medicine, population survey research, pulmonary, mental health, behavioral medicine, chronic diseases and exposure science. SAC members provided significant input and advice on the surveys, including recommending specific mental health scales for depression, anxiety and GERD and questions related to history of trauma. They were also consulted about cancer and mortality assessments and multiple Registry analyses of Wave 2 survey data.

The CAB includes representatives from affected communities in lower Manhattan, including residents, community boards, and downtown workers. The CAB provided feedback on surveys as well as analyses related to responder volunteers, residents, area workers and children; Registry communications materials; outreach strategies to various affected communities (e.g., Spanish and Chinese-speaking and lower Manhattan enrollees); and direct assistance in improving response rates among enrollees.

The LAC has representatives of private and public unions, including uniformed and non-uniformed workers, and other labor organizations. LAC provides ongoing expertise and advice on a number of issues, including feedback on health concerns and effective ways to communicate with affected workers (e.g., rescue/recovery, utility, construction workers); the development of the Staten Island and barge workers survey; and the effort to identify common exposure metrics across the WTC programs. LAC members also made Wave 3 survey information available for their unions via website postings and newsletters.

9-11 Health Info website: The NYCDOHMH WTC Health Coordinator created the website www.nyc.gov/9-11HealthInfo to provide a comprehensive “one-stop shopping” site for all 9/11 related findings, information, resources and services. Google ranks the site first for people using the search term “9/11 health.” Regularly updated, the website has direct links to the websites maintained by the federal WTC Health Program and the federal September 11th Victim Compensation Fund (VCF) since these programs were implemented in 2010 after passage of the Zadroga 9/11 Health and Compensation Act. Core content, including brief descriptions of the Zadroga Act, the WTCHP and the VCF, and core Registry content, is translated into Spanish, Chinese and Polish. In conjunction with the 9/11 health website, the WTC Health Coordinator publishes bimonthly a 9/11 health electronic newsletter, which eliminated the need for Registry print newsletters and resource guides.

The 9-11 Health Info website also includes the annual reports from the World Trade Center (WTC) Medical Working Group (MWG), which was appointed by Mayor Bloomberg in June 2007. The WTC MWG reviews the latest medical research on potential health effects of the WTC attacks, reviews the adequacy of health and mental health services available to WTC-exposed persons, and advises city government on approaches to communicating health risk information.

The Registry’s web page, located on the 9-11 Health Info website, is updated regularly, in collaboration with the WTC Health Coordinator’s office. Many of the Registry materials sent to enrollees via email or mail are posted on the 9-11 Health Info website for the public (e.g., Annual reports, Summary of Rights, and Treatment Referral Project brochures). Other materials are only posted on the website (e.g., physician guidelines, abstracts of Registry published manuscripts, a map of enrollees by state).

Communications with Enrollees and the Public: The Registry continued to disseminate Registry health findings and 9/11-related information through various communications to enrollees, the public and policy makers (Aim 3a), to inform enrollees of 9/11-related services, resources, and health promotion programs (Aim 3b) and to keep them informed, engaged and interested in Registry activities (Aim 1b). (These communications are in addition to those listed in Section 2, Aim 1 above.) All key communications materials were available in English, Chinese and Spanish.

Aim 3b: Inform enrollees of 9/11-related services, resources, and health promotion programs
The many ways we implement this aim are described in Section B, Methods, Aim 3a and 3e.

Aim 3c: Develop and provide Registry data resources for, and respond to inquiries from, for enrollees and the public

The Registry maintains data resources for enrollees, the public and external researchers that are accessible via the Registry's web page on the 9-11HealthInfo website, including Waves 1-3 adult and pediatric surveys, a Wave 1 Data File User's Manual (DFUM), and an interactive health query data tool. The 9/11 Health Online Data Tool, available at the " 9-11 health info" website, permits users to examine de-identified baseline survey data by crossing any two demographic, eligibility group, exposure, health condition, or rescue and recovery organization or agency variables. Since 2009, this data tool has been accessed nearly 2,000 times by users outside NYCDOHMH. This tool will be updated with Wave 2 data in 2012.

Staff have also run many data queries for external researchers, policy makers, collaborators, and members of the press and public, and create de-identified data sets for approved external research projects. Considerable staff resources are invested in running data queries to help address research issues or inform policy.

Aim 3d: Develop and disseminate updated 9/11-related treatment guidelines for physicians and other providers

The *Clinical Guidelines for Children and Adolescents Exposed to the WTC Disaster* was published by NYC DOHMH as a City Health Information booklet in July 2009. The NYC WTC Medical Working Group and Registry staff have reviewed the medical literature for new and emerging health conditions or treatment recommendations for 9/11-exposed populations on a regular basis. Although there have been many articles since the publication of the WTC clinical guidelines for treatment of adults (2008) and children and adolescents (2009), these guidelines remain clinically relevant.

Aim 3e: Offer healthcare referrals to enrollees with identified healthcare needs

By responding to health concerns and needs of individual enrollees, we have potentially promoting long-term participation of enrollees and maintenance of the Registry as a whole to further all of the Registry's aims.

The Tobacco Cessation Project: Several published studies indicating that smoking rates increased in populations exposed to the WTC disaster, including firefighters, prompted us to implement a tobacco cessation project in 2008-10 in collaboration with the NYC DOHMH Bureau of Tobacco Control. This

NYC-funded project completed active outreach to all adult NYC residents, out of state residents and NYC government employees who indicated that they were current smokers on the most recent Registry survey available. NYC residents were offered in-person counseling and nicotine replacement therapy (NRT) kits or prescription medication. NYC government employees and enrollees residing outside of New York State (NYS) were offered telephone counseling and NRT kits by mail. NYS residents received information on the benefits of smoking cessation and a referral to the NYS Quit Line. Letters were also sent to all NYC smokers each spring referring them to the annual NYC nicotine patch and gum give away.

The 9/11 Treatment Referral Program (TRP): The first three years of the Registry's TRP was funded by a subcontract from NYC Health and Hospital Corporation (HHC) under a NIOSH grant awarded in 2008 to HHC's WTC Environmental Health Center Survivor Program (EHC SP) to provide care at no cost to eligible WTC survivors (lower Manhattan residents and area workers). Since Sept. 2011, TRP has been supported by core Registry funding from NIOSH.

TRP staff conducted personalized outreach to English language adult enrollees residing in NYC who reported physical or mental health symptoms or conditions on the Registry's Wave 1 or Wave 2 surveys, and were potentially eligible for HHC's WTC EHC SP. TRP staff also conducted outreach to parents/ guardians of all pediatric enrollees residing in NYC. Outreach consisted of a mailing (personalized letter, brochure and reply card) and telephone follow-up. TRP staff followed up with interested enrollees, completed the intake form for EHC, scheduled appointments, made reminder calls and if requested, escorted enrollees to their appointment. Staff kept EHC and the community apprised of TRP progress via presentations at EHC and Registry advisory board meetings and helped plan an EHC forum in lower Manhattan on 9/11-related services.

The cornerstones of TRP are its personalized approach to outreach and its evaluation efforts. Staff have been trained in motivational interviewing, a technique that focuses on the processes within an individual that facilitate behavior change or adaptation, which helped to identify barriers to utilizing 9/11-related services. This approach has strengthened the Registry's ability to address enrollee needs and make effective referrals. Early on, we consulted with HHC clinicians and experts in mental health and WTC-related health issues for guidance on which reported respiratory and mental health symptoms and conditions to use in selecting priority groups for TRP outreach.

Under the Zadroga Act, the Responder and Survivor programs are now under the federal WTCHP, effective July 1, 2011. Enrollees targeted for TRP outreach now receive a WTCHP application to submit on their own. TRP staff continues to assist with completing the form and answer questions about enrollment, eligibility and documentation and continue to coordinate closely with EHC.

TRP has also been providing comprehensive and timely follow-up to address health problems, concerns and questions reported by enrollees on the Wave 3 survey, including distress during the telephone interviews. Follow-up includes a personalized letter and the WTCHP application or a phone call as appropriate.

To prepare for a planned expansion of TRP to include outreach to enrollee responders eligible for the WTCHP, a pilot mailing with the WTCHP application was sent to ~500 enrollee responders who reported physical health symptoms on the Wave 3 survey. The pilot has yielded 126 contacts to-date. In Feb. 2012, the Registry's Medical Director presented to the WTC Responder Program Steering Committee our plan to coordinate with the WTCHP to expand TRP to include responders. We are currently soliciting feedback on TRP outreach materials and plans from WTC Responder Program sites (e.g., Mt. Sinai Medical Center). TRP staff has also provided feedback on NIOSH's master plan for

WTCHP outreach which includes TRP, and reviewed enrollment and outreach materials for the Responder and Survivor Programs and the Responder Outreach Coordination Committee.

Evaluation across all Aims

Of central importance to our progress and productivity during the three year funding period was our ongoing monitoring and evaluation of all Registry activities, using several strategies. For example, a comprehensive manuscript database tracks all ongoing research, from conceptualization through dissemination of findings. We prepared periodic reports to track the manuscript development processes ensuring stringent quality control while producing information that is clear, timely, and relevant. We exceeded our goal for the number of manuscripts submitted in Years 01-03, supporting our dissemination of information to inform policy decisions about 9/11-related services. Recording of meetings, presentations, and other communications with each of our several advisory boards has helped ensure that input from experts and other interested parties has been obtained and incorporated into Registry products. Ensuring input from all appropriate sources has been especially useful to our development of the Wave 3 survey. A separate evaluation system was maintained by the Registry's Treatment Referral Program to enable continual monitoring of process and outcomes appropriate to enrollees whose survey responses indicate specific health-care needs. We constantly updated our unified central database, which includes up-to-date contact and other identifying information to help to maintain the Registry and maximize survey response. Each of these evaluation strategies allows us to maintain our focus on reducing illness, facilitating access to treatment and services, and improving the health status of those exposed to the events of 9/11.

D. Results and Discussion

AIM 1: Maintain the Registry as a valuable public health resource

Aim 1a: Maximize the number of enrollees with valid, updated contact information through ongoing communications and tracing activities to locate enrollees lost to follow-up

The table below summarizes all contact information updates received to-date during Years 01-03.

Table 1: Contact information updates received in Years 01-03 by type and source

Type of Update	Source of Contact Information Update Received by the Registry								
	Calls	**Email**	**Fax**	**Letter**	**Web**	**Other***	**NCOA ***	**RTI**	**Total**
Address	3,428	710	5	6,451	785	12,203	5,672	12,198	41,452
Phone number	5,319	1,299	15	15,975	717	6,876	22	8,397	38,620
Email address	2,666	1,673	3	7,712	559	345	7	609	13,574
Total	11,413	3,682	23	30,138	2,061	19,424	5,701	21,204	93,646

*Other sources include updates from earlier matches to the US Postal Service's National Change of Address (NCOA) and from early tracing conducted by RTI International, the Wave 3 survey vendor.

In sum, over 47,000 updates to contact information were directly received from enrollees (via the first five sources in the table above) and over 46,000 updates were received from other sources.

Enrollee Tracing: Batch and intensive tracing activities conducted during this time period to obtain updated and/or missing contact information for enrollees include:

1) In 2009, staff conducted intensive tracing of all in the tracing queue, reducing it from ~6,500 to ~4,200.
2) In early 2011, RTI conducted batch tracing of the entire tracing queue, the "presumed active" enrollees (whom we've not heard from in the past ~ 5 years), and the ~19000 enrollees without valid home telephone numbers. This effort reduced the tracing queue from 6,591 to 1,852 enrollees, reduced currently lost enrollees from 2,356 to 831, and located over 6,300 home telephone numbers.
3) In 2011, RTI conducted intensive tracing of the remaining and newly added enrollees in the tracing queue. This effort reduced the tracing queue from ~4,300 to 1,633 enrollees, including 195 currently lost enrollees.
4) In late 2011 and early 2012, several smaller priority groups of enrollees were sent to RTI for batch and intensive tracing (e.g. pediatric enrollees, enrollees in CATI without valid phone numbers). RTI provided a tracing recommendations report with specific methods that the Registry will implement beginning in Year 04.
5) In 2012 the Registry reached out to tracing vendors in RTI's tracing recommendations report and began working with the largest vendor, Lexis Nexis, to set up an agreement for a trial use of Lexis Nexis to conduct tracing of individual enrollees in our tracing queue. After the trial is completed, the Registry will determine whether to pursue ongoing tracing activities with Lexis Nexis.

The Registry's tracing queue is now 1,748 enrollees, including 251 currently lost to follow-up. The Registry will evaluate and begin to implement in Year 04 the other tracing recommendations in RTI's report.

Current Status of Enrollees: As shown in Table 2 below, during Years 01-02 we achieved our goal of increasing the number of active enrollees and decreasing the number of currently lost enrollees prior to the launch of the Wave 3 survey in June 2011. We continued this trend in Year 03 during the implementation of the Wave 3 adult survey, so by the end of the adult survey in March/April 2012, "*active*" enrollees had been increased to 59,889 (83.84% of all enrollees) and "*currently lost*" enrollees had been decreased to 291 (0.41%). This measure of "*active*" enrollees reported those enrollees with whom we have had direct contact with since November 1, 2006, the start of the Wave 2 survey.

The active date was modified ("reset") beginning in July 2012 to reflect active status as of the beginning of the Wave 3 survey, June 1, 2011. Hence, enrollees are currently counted as "*active*" if we have had direct contact with them on or since June 1, 2011. Enrollees with whom we have not had direct contact with since June 1, 2011 (and who are not "*deceased", "currently lost" or "withdrawn*") are considered "*presumed active*". The last column of Table 2 below reports current enrollee status as of July 2012.

Table 2: Enrollee status by project year

Enrollee Status	Year 01 (2009-10)		Year 02 (2010-11)		Year 03 (2011-12)				% As of Jul-12
	Apr-09	Dec-09	Apr-10	Dec-10	Apr-11	Dec-11	Apr-12	Jul-12	
Deceased	1,016	1,081	1,113	1,135	1,281	1,606	1,806	1,841	2.58%
Withdrawn	283	305	308	308	317	508	736	755	1.06%
Currently Lost	1,481	2,415	2,391	2,355	619	305	291	252	0.35%
Active *	49,082	51,908	53,614	53,970	57,618	59,944	59,889	48,355	67.69%
Presumed Active*	19,575	15,728	14,007	13,669	11,602	9,071	8,712	20,231	28.32%
Total	71,437	71,437	71,437	71,437	71,437	71,434 **	71,434	71,434	100%

** The active date was modified beginning in July 2012 to reflect active status as of the beginning of the Wave 3 survey, June 1, 2011. Previously, active status was measured as of the start of the Wave 2 survey, November 1, 2006.*
*** Three duplicate enrollee records were identified and removed from the database.*

In sum, most enrollees are currently active (68%) and very few have withdrawn (~1%) or are lost to follow-up (~0.35%).

Aim 1b: Maintain timely, accurate and professional communications and feedback with enrollees to address concerns and keep them engaged and interested in participating in future research

Respond to incoming communications: From April 2009 through the end of the Wave 3 adult survey in March 2012, Panel Maintenance (PM) unit staff typically received more than 50 incoming communications daily, Monday-Friday from 9am-5pm, and replied within one business day. Since March 2012, incoming communications to the PM Unit has decreased to about 15 per day. Since April 2009, PM staff have responded to over 66,000 incoming communications, primarily from enrollees, including ~13,300 telephone calls to our local and toll free numbers (~11,400 to provide updated contact information and ~1,900 to request 9/11 resource information), ~9,600 emails and ~30,150 letters and faxes. These counts exclude the additional inbound communications to our tobacco cessation and treatment referral programs (see Section 2. Results. Aim 3e below). Registry staff confirmed enrollee contact information during every telephone contact with enrollees. Additionally, NYC's 311 line, a 24/7 source of information about city services has responded to nearly 3,000 9/11-related calls.

Provide regular outreach and feedback: Since April 2009, PM staff sent ~704,250 emails and ~968,000 pieces of mail to enrollees to keep them engaged, and to provide information including:

- Annual New Year Cards with reply cards (for contact information updates) and Annual Reports
- Adult and Pediatric Wave 3 survey materials (e.g., paper surveys, email invitations, postcard and email reminders and thank you letters & emails)
- Staten Island and Barge workers survey materials and thank you letters
- Letters to request email addresses and to convert more enrollees to "active" status
- Personalized mailings to clarify discordant demographic information (e.g., gender, date of birth, first and last name information that was reported to the Registry on different Wave 1, 2 or 3 surveys)
- Summary of Rights to all enrollees including child enrollees who reached 18 years of age
- Recruitment information for ancillary studies by external researchers and the Active Referral Program
- Bi-monthly 9/11 e-newsletters and other communications (see Section 2. Results. Aim 3 below).

Aim 1c: Conduct outreach to boost response to Registry studies

Registry staff conducted numerous outreach activities to enhance response rates to the Registry's Wave 3 adult and pediatric surveys and the Staten Island and Barge Workers Survey,

Media outreach: As a key component to outreach, we implemented a Wave 3 media strategy to promote Wave 3 survey participation. The DOHMH press office disseminated three press releases announcing the launch of the adult and/or pediatric surveys, one press release to announce the deadline of the adult Wave 3 survey, four news articles were published in Lower Manhattan downtown publications regarding the Adult survey, an additional four articles were published in these publications (e.g., DNAInfo, Downtown Express, Tribeca Trib, and Downtown Broadsheet) about the Pediatric survey, and a public service announcement ran during February 2012 on 1010 WINS radio, a local CBS news station, to promote Wave 3 survey participation.

Reminder telephone calls: Outreach activities included two rounds of automated Wave 3 reminder calls conducted by Global Strategies Group (GSG), a NYC DOHMH communications vendor, first to adult enrollees and later to parents/guardians of pediatric enrollees who had not yet completed a Wave 3 survey. GSG made over 69,000 automated Wave 3 reminder calls between September 2011 and February 2012. GSG also made personalized reminder calls to 1,700 non-respondents of the Staten Island and Barge Workers Survey.

In May-June 2012, Registry staff made a third round of personalized reminder telephone calls during weekday evenings to 632 parent/guardians of enrollees who had not yet completed their Wave 3 Pediatric survey.

Community presentations and outreach to residential buildings in Lower Manhattan: To boost response to the Wave 3 Adult survey, Registry staff set up tables in building lobbies and conducted door-to-door outreach in lower Manhattan because downtown residents had lower response rates compared to Responders. Our Public Affairs Liaison obtained advice and assistance from our Community Advisory Board members and Community Board 1 in gaining access to the 43 large downtown residential building complexes with the highest numbers of enrollees who had not yet completed their Wave 3 adult survey (n~1,300 total enrollees). In the fall of 2011, informational tables in 11 downtown building lobbies were staffed during weekend days and weekday evening hours to provide resident enrollees with information on the survey and 9/11-related health resources

To boost response to the pediatric survey, the Registry also conducted community presentations and localized media pitching in lower Manhattan, including a presentation at the Manhattan Community Board 1 Youth and Education Committee in July 2012, where we promoted the importance of the survey.

Door-to-door outreach: Wave 3 Adult survey: In the winter of 2012, intensive door-to-door outreach was successfully conducted by English, Spanish and Chinese (Mandarin, Cantonese) speaking staff teams who either spoke directly with enrollees and provided surveys upon request, or slipped language-specific survey reminder flyers under their doors. Over 200 face-to-face conversations with enrollees occurred and over 750 flyers were disseminated. Other DOHMH staff assisted in this effort with financial support from the Division of Epidemiology.

Door-to-door outreach: Wave 3 Pediatric survey: During Year 04, from July-August 2012, the Registry successfully conducted similar door-to-door outreach to parents/guardians of enrollees who had not yet responded to the Wave 3 pediatric survey. Intensive door-to-door outreach was conducted during weekday evening hours and on the weekend by English, Spanish and Chinese (Mandarin, Cantonese) speaking staff teams who either spoke directly with parents/guardians and provided surveys upon request, or slipped language-specific survey reminder flyers under their doors. Over 100 face-to-face conversations with parents/guardians occurred and nearly 100 flyers were disseminated.

To further enhance response rates to the Pediatric survey, the Registry twice extended the deadline for survey submissions, and added an incentive of a $10 Barnes and Nobles gift card as a thank you to adolescent enrollees who participated in the survey.

AIM 2: Expand knowledge about the long-term health effects of the 9/11 disaster by continuing the WTCHR research program

Aim 2a: Describe the health of enrollees and quantify risk factors for adverse health conditions by conducting priority analyses based on the 2003-04 and 2006-07 surveys

We broke new ground in describing and quantifying co-morbid physical and mental health conditions and their evolution over time, reported on cancer and mortality incidence 7-8 years after 9/11, and provided a unique study of respiratory effects among residents. We used qualitative methods to lay the groundwork for future studies of Staten Island landfill/barge workers, about whom little is known, and of enrollees who participated in the Registry's Treatment Referral Program (TRP). We reported on health care access and unmet mental health care needs and published several reviews and commentaries, including a review to inform disaster policy, and we also reported on emerging conditions, including sarcoidosis and GERS.

The Registry's publication history may be summarized as follows:

Table 3: Summary of Registry Manuscripts as of July 8, 2012	**No. of Manuscripts**
Published prior to this 3 year reporting period	**7**
Published or submitted during this 3-year reporting period	**26**
Published journal articles (n=22) or book chapter (n=1)	23
Submitted, awaiting editorial decision at journal	3
Originally proposed in the Registry's Years 01-03 plan	17
Published or submitted	**15**
Postponed until Years 04-07 (Injury, PTSD trajectory)	2
Additional manuscripts published or submitted	**11**
Total manuscripts published or submitted to date	33

A total of 26 manuscripts have been published or submitted during the three year time period of this award. Fifteen out of the original ~17 manuscripts in the 3-year proposed publication plan have been published or submitted for publication, as well as an additional eleven manuscripts.

Two manuscripts on the original publication plan - *PTSD Trajectory*, and *Injuries*, have been postponed into the current funding period (Years 04-07) in order to focus on the eleven new added manuscripts that were considered to be of a higher priority during Years 01-03. The topics of these eleven added manuscripts include the following: (a) additional emerging conditions (GERS, skin rash), (b) disaster policy lessons, (c) a focus on PTSD in specific populations with external collaborators (e.g., tower survivors, and police), (d) special topics (e.g., nanomaterials), and (e) ten-year anniversary of 9/11 manuscripts (e.g., in Lancet and JAMA)

Besides the manuscripts listed in Table 1 above, there are 5 additional draft manuscripts circulating among co-authors (including the *Injury* manuscript) and 16 analyses for manuscripts actively in progress (including the *PTSD Trajectory* manuscript).

Summary of key findings:

A brief summary of key findings for each of the 23 published articles is listed below as well as a brief description of the submitted cancer findings manuscript. References for the articles cited here are listed in *Section 2F: Publications* of this report.

Residents, area workers and passersby with intermediate or high levels of WTC exposure, including those with two or more injuries on 9/11, had elevated all-cause and heart disease mortality risks compared to those with lower levels of exposure. No WTC exposure-related mortality differences among rescue/recovery workers were detected. (*Jordan et al.*, 2011)

An exploratory study found that 2-6 years after 9/11, measures of dust exposure, injury on 9/11 and PTSD were each associated with an elevated risk of non-fatal heart disease among adult enrollees (*Jordan et al.*, 2011).

Among rescue/recovery workers (RRW), the standardized incidence ratios (SIRs) for multiple myeloma, prostate and thyroid cancers were significantly elevated in 2007-08. No increased SIRs were observed among non-RRW in 2007-08. None of the cancers examined, including the three with elevated SIRs, was associated with intensity of WTC exposure. We will follow-up to see if these findings persist or not. (*Li et al*., 2012]

More than 25% of residents, area workers and passers-by enrolled in the Registry who had either lower respiratory symptoms or probable post-traumatic stress disorder (PTSD) reported that they had *both* conditions 5-6 years after 9/11. Enrollees with both conditions were more likely to report 14 days of activity lost in the 30 days before being surveyed than enrollees with one of these conditions (*Nair et al*., 2012).

A review of short- and mid-term health effects found strong evidence for association between 9/11-related exposures, and PTSD and respiratory illness. Continued follow-up of exposed adults and children is needed to track illness over time, and to detect potential late emerging illnesses (*Perlman* et al., 2011). Ten years after the attacks, a commentary briefly reviews what is known regarding the health effects, outlines important questions that remain unanswered, describes current provisions for care for those affected, and discuss lessons learned for future disasters. (*Thorpe et al*., 2011).

Rescue and recovery workers who wore respirators on 9/11 were less likely to report respiratory problems five to six years after 9/11 than those who went without adequate respiratory protection (*Antao et al*., 2011). A nested case control study found that working on the WTC debris pile significantly increased the sarcoidosis risk for rescue and recovery workers; no risk factors were identified for other groups. (*Jordan et al.*, 2011).

A case control study of ~800 residents and area workers found that both acute and chronic WTC exposures were independently associated with lower respiratory symptoms up to six years after 9/11. The risk increased both with the severity of dust cloud exposure and the thickness of dust in the home or workplace (*Maslow et al*., 2012). Residents and area workers with persistent respiratory symptoms were more likely to have abnormal lung function than those without these symptoms 5-6 years after 9/11 (*Friedman et al*, 2011).

Among adult enrollees, 13% reported new gastroesophageal reflux symptoms (GERS) that had persisted up to 6 years after 9/11. GERS were positively associated with higher levels of WTC exposure, asthma and PTSD but occurred even among enrollees who didn't report asthma or PTSD, suggesting for the first time an independent association with WTC exposure. (*Li* et al., 2011). Among enrollees without PTSD or other psychological distress, increased risk for early skin rash was associated with intense dust cloud exposure, damage to the home or workplace, and working at least 31 days at the WTC site (*Huang* et al., 2012).

Among police responders, PTSD prevalence doubled from 7.8% in 2003/4 to 16.5% in 2006-07. Females were significantly more likely than males to report PTSD symptoms in 2003/4, but this gender difference disappeared by 2006/7. Older age and 9/11-related injury increased the risk of PTSD. (*Bowler* et al., 2010; *Bowler* et al*.,* 2012). Registry enrollees with probable PTSD were more likely than women without PTSD to deliver premature or underweight babies (*Lipkind et al.*, 2011). WTC tower survivors who evacuated from higher floors, evacuated late or worked for a company that sustained fatalities were at higher risk for PTSD (*DiGrande et al.*, 2011). Volunteers not affiliated with an organization were more highly exposed to the WTC disaster than volunteers affiliated with recognized organizations, and were more than twice as likely to have had chronic PTSD, late-onset PTSD, or new or worsening lower respiratory symptoms (*Debchoudhury et al*., 2011).

In focus groups with both responders and survivors, participants reported lack of visibility and accessibility of 9/11 health programs; fear of stigma related to receiving mental health care ;

unfamiliarity with 9/11-related health conditions; and few referrals from primary care providers were barriers to accessing 9/11 health care services (*Welch* et al., 2012).

Researchers derived estimates by taking rates among enrollees of self-reported new diagnoses of asthma and posttraumatic stress symptoms 5-6 years after 9/11, and applying these rates to an estimated population of people who were most heavily exposed to the WTC disaster. Among the ~409,000 persons most heavily exposed, by 5 to 6 years after 9/11, ~17k-40k adults may have been newly diagnosed with asthma and ~ 43k-88k adults may have experienced PTSD symptoms (Brackbill, 2009).

A comprehensive description involved in the creation of the WTC Health Registry, from design through implementation, was outlined along with lessons learned. This provided important lessons for the possible creation of a nanomaterials exposure registry (*Cone et al*., 2011).
A summary of the NYC DOHMH's response to the 9/11 disaster, including subsequent preparedness activities, lessons learned, post 9/11 mental health intervention services, and development of the WTCHR (*Weisfuse et al*., 2011).

This qualitative study involved in-depth interviews of workers who participated in the recovery and cleanup efforts at the WTC Recovery Operation at Fresh Kills Landfill after the 9/11 terrorist attacks. The study provided unique insight into the experiences, exposures and concerns of understudied 9/11 recovery and cleanup workers (*Ekenga et al*., 2011).

Aim 2b: Develop and conduct a second follow-up survey ("Wave 3") to ascertain the health status of the cohort 10 years after 9/11

Adult Wave 3 Survey (2011-12): A total of 43,135 adult surveys were completed out of a final denominator of 68,361 for a final response rate of 63.1%. The surveys were completed by mail (n=17,512), web (n=19,221) and CATI (n=6,402). The data set was cleaned by RTI and Registry staff collaboratively; counts are provisional. A draft Wave 3 data file user's manual (DFUM) was completed by RTI International and Registry staff. The Wave 3 Adult survey final analytical data set and DFUM will be completed in Year 04.

Mode experiment: Response rates of 34.5%, 39.6% and 43.0% were achieved for the web, mail and CATI experimental groups, respectively. Beginning in January 2012, cases were offered the remaining two mode options. Final response rates of 65.3%, 58.5%, and 59.8% were achieved for the cases in the web, mail and CATI experimental groups, respectively.

Response rates: The preliminary response rate (RR) for eligible Wave 3 enrollees (n=68,361) is 63.1% and much higher (77.8%) among the 46,224 Wave 2 participants. Preliminary RRs varied by age and eligibility group. Older enrollees had higher RRs than younger enrollees (~70% for 65+ and ~32% for 18-24 year olds). Similar to Wave 2, residents had the lowest Wave 3 RR (~53%) and rescue/recovery workers had the highest (~65%).

With input from Registry staff, RTI produced an outcomes rate report in Year 03 based on American Association for Public Opinion Research (AAPOR) methods.

Pediatric Wave 3 survey (in progress): As of October 18, 2012, the Registry has received 558 (41.6%) parent surveys, 484 (36.1%) adolescent surveys and a total of 466 (34.8%) paired parent and adolescent surveys. To boost response, the Registry implemented up to 5 rounds of personalized paper survey mailings, monthly email and postcard reminders (up to 10 and 11, respectively), and door-to-door outreach (which was effective during Wave 2) with a focus on non-respondent enrollees in lower Manhattan. Data collection will continue through at least October 2012.

Aim 2c: Complete initial cancer and mortality assessments

Highlights: During the three-year period of this cooperative agreement, we have conducted multiple rounds of record linkages to the NYC Vital Records (n~3 rounds), the National Death Index (n~3 rounds), the Social Security Administration Death Master File (n~2 rounds) and 11 state cancer registries (NY, NJ, CT, PA, OH, MD, WA, NC, TX, CA, and MA) (n~2 rounds) to assess mortality and cancer, respectively, among the ~71,000 Registry enrollees. Because of the delays in reporting of deaths and cancers to these registries, the multiple rounds of record linkages resulted in mortality updates to Registry records through 2008 (for NDI), 2009 (for NYC Vital Records) and 2011 (for SSA) and cancer updates to Registry records through 2008.

The Registry also completed other related activities during the three year cooperative agreement period, including: developed and implemented a protocol and algorithm for manual review of mortality record linkage results; conducted a cancer validation study; and co-sponsored with the WTC Centers of Excellence (FDNY, Mt. Sinai and Bellevue) a Cancer and Mortality Methods Workshop and Follow-up to develop recommended methods for cancer analyses, and an Analytical Methods Workgroup to develop a common WTC exposure matrix across the WTC cohorts.

Cancer Assessment: Cases of first primary invasive cancer identified through the matches to state cancer registries were used for the Registry's first cancer study. This early study found significantly increased SIRs among rescue/recovery workers for prostate and thyroid cancers and myeloma in the 2007-2008 time period, although the SIRs were not significantly associated with WTC exposures. Increased risk for prostate and thyroid cancers was also found in the FDNY study among exposed firefighters despite differences in study methods. This first manuscript on cancer was submitted to a peer-reviewed journal in Feb. 2012 (*Li et al., 2012).*

Cancer Validation: Registry staff conducted medical record review and/or clinical confirmation of self-reported cancers for those enrollees who reported cancer to the Registry but who did not match to a state cancer registry. Registry staff contacted 1,435 enrollees to secure permission to access their medical records and/or speak with a medical provider. A total of 117 cancers, out of 172 enrollees who provided permission, were confirmed through this process.

Mortality Assessment: We conducted matches to the NDI and obtained mortality records through 2008, the SSA Death Master File to obtain records through 2011, and the NYC Vital Statistics to obtain records through 2009. The resulting data were included in the Registry's first published mortality study focused on 2003-09 deaths among Registry enrollees who resided in NYC at Wave 1 (*Jordan* et. al., 2011). We found that fewer deaths occurred among Registry enrollees than expected based on comparison to the general NYC population. This may be due to healthy worker and volunteer effects in the Registry cohort. We also found that among non-rescue/recovery enrollees higher levels of 9/11-related exposure were associated with all-cause and heart-disease-related mortality, results which require confirmation through additional follow-up.

2010 Cancer and Mortality Methods Workshop and Follow-up: The Registry assisted in the planning and attended this workshop. Nationally recognized experts in cancer epidemiology, environmental health and biostatistics from around the U.S. attended and provided advice on how best to proceed with cancer studies of 9/11-exposed populations.

Subsequent to the Methods Workshop, the Registry participated in a series of meetings with the WTC Centers of Excellence to discuss development of a common exposure matrix, cancer definitions and resolving cancer ascertainment and jointly developed two related abstracts that were presented at the 2011 CSTE conference (*Zeig-Owens et al., Weakley et al*.,; See *Section 2G: Presentations*). A limited number of exposure measures available in common among rescue and recovery cohorts were identified: dust exposure on 9/11, work periods at the WTC site, and work activities on the debris pile.

Aim 2d: Identify and investigate potential emerging health conditions

The Registry has investigated emerging health conditions based on results of the Wave 2 survey (including GERS and the 2009 Brackbill paper), published reports from other cohorts (sarcoidosis, skin rash), and results of our mortality study (heart disease). In addition, the Registry has performed in-depth investigations of specific cancer types reported by clinicians from the WTCHP (e.g., hematological malignancies) and reported by medical directors of private companies involved in WTC cleanup (e.g., thyroid cancer). The Registry published manuscripts based on investigations of many of these conditions (e.g., GERS, sarcoidosis, heart disease, skin rash) (See *Section 2F: Publications*).

We also successfully linked Registry records to the NYS hospitalization data (SPARCS) in Year 03 to evaluate the incidence of other potential 9/11-related emerging health conditions, including chronic diseases.

Aim 2e: Facilitate independent and collaborative research by sharing data and resources with WTC Centers of Excellence and qualified academic researchers

The Registry has had multiple research collaborations with the WTC Centers of Excellence that comprise the WTCHP and other external researchers including collaborative in-depth studies, analyses of Registry survey data, and studies in which the Registry facilitated enrollee recruitment on behalf of external researchers.

During this three year cooperative agreement, the following research collaborations occurred: (Publications that are mentioned are briefly described in *Section 2,* Results *Aim 2a* above and are listed in *Section 2F: Publications*.)

Joint extramural collaborations, Years 01-03

Respiratory case-control study of residents and area workers. Registry PIs: S. Friedman, C. Maslow. External collaborators: J. Reibman, K. Berger, R. Goldring (NYU School of Medicine/Bellevue WTC Center of Excellence). Results have been published (*Friedman et al*., 2011). The follow-up investigation provided an opportunity to determine whether these same residents and area workers continue to experience lower respiratory symptoms and whether their lung function has improved or worsened over the past 3-4 years (*Maslow et al.*, 2012).

Cooperative development of exposure and cancer study methodology. Registry PIs: R. Brackbill, J. Cone, C. Farfel M, Maslow. External collaborators: D. Prezant (FDNY), L. Stevenson (Mt. Sinai School of Medicine), M. Siegel de Hernandez (Communications Workers of America), J. Reibman (Bellevue WTC Center of Excellence). Representatives of four NYC based WTC cohort studies met to harmonize approaches to measuring WTC-related exposures and cancer assessments in their respective cohorts in order to improve comparability. Consensus findings were presented at the 2011 Conference of State and Territorial Epidemiologists (see *Section 2G: Presentations*).

Nested case-control study of sarcoidosis. Registry PI: H. Jordan. External collaborators: A. Teirstein (Albert Einstein College of Medicine), D. Prezant (FDNY). A case-control study of 43 biopsy-proven cases of sarcoidosis and 109 controls found that working on the WTC debris pile was associated with an elevated risk. Results have been published (*Jordan et al.,* 2011).

WTC Skin Rash study. Registry PI: J. Cone, J. Li. External collaborators: M. Huang (Emory University), D. Cohen (NYU School of Medicine). Skin rash was associated with direct exposure to the WTC disaster and continued exposure from damaged workplaces and homes. Results have been published (*Huang et al*., 2012).

Cardiovascular disease incidence. Registry PIs: H Jordan, J Cone. External collaborator: A Morabia (Queens College, CUNY). There were 1,162 incident heart disease cases among 39,324 adult enrollees followed for nearly 3 years. CHD risk was associated with intense dust cloud exposure and injury, and dose-related to PTSD. Results have been published (*Jordan et al*., 2011).

Physical and mental health among police responders. Registry PI: J Cone. External Collaborator: R. Bowler (San Francisco State University). Studies of 4,017 police responders at Wave 1 and 2,527 who also participated in Wave 2 showed a continued high prevalence of PTSD and comorbidity with other mental health outcomes. Results have been published (*Bowler et al*., 2010; *Bowler et al*., 2012).

Cognitive function among WTC survivors. Registry PIs: R Brackbill, S Stellman. External collaborators: L Anderson, W Pearson (CDC Div. of Adult and Community Health). CDC researchers with expertise in aging studies requested that the Registry add several questions on cognitive function to the Wave 3 questionnaire. After several rounds of consultation, a set of four questions was incorporated into Wave 3. This adds an important dimension of quality of life for future studies.

Binge drinking in relation to WTC exposure. Registry PI: A Welch. External collaborators: D Hasin, K Keyes (Columbia University). This analysis seeks to describe patterns of binge drinking among enrollees and their relationships with 9/11 exposures. Preliminary data were presented to the Labor Advisory Committee on January 31. A manuscript is in preparation.

Smoking and serious psychological distress among Registry enrollees. Registry PI: A Welch. External collaborator: M Johns (NYCDOHMH, Bureau of Tobacco Control). This analysis seeks to describe the relationship between smoking and serious psychological distress as measured by the Kessler (K-6) scale. A manuscript is in preparation.

Respiratory health outcomes and home conditions of lower Manhattan residents enrolled in the WTC Health Registry. Registry PIs: Cone, Farfel, Stellman, Maslow, Walker. External collaborators: V Antao, L Pallos (ATSDR). Using data from Module A of the Wave 2 questionnaire that was completed by over 6,000 lower Manhattan residents, we will describe the relationship between respiratory health outcomes and extent of 9/11-related home damage and cleanup. GIS methods will augment existing data on residential proximity, orientation, and height above street level relative to the WTC towers' collapse to better understand the nature of home damage and debris. Analysis is ongoing.

Studies with Registry-facilitated recruitment

Violence and mental health: children of first responders. PI: Christina Hoven (Columbia University and NY State Psychiatric Institute). With the facilitation of the Registry, Dr. Hoven's group has interviewed a total of 546 children, age 8-15, of first responder enrollees (fire, police, EMT) or evacuees in their homes. Measurement instruments included Disc Predictive Scales to assess PTSD, major depression, generalized anxiety disorder, and several other psychological outcomes. Analyses in collaboration with Registry staff that will assess child mental health status in relation to both child and parent WTC experiences are in progress. This study is an outgrowth of Dr. Hoven's NICHD funded grant HD-046786 with the same title. A description of the study has been published.

Combination Treatment for PTSD. PIs: F Schneier, E-J Suh (Columbia University and NY State Psychiatric Institute). Adult WTC survivors were randomly assigned to 10 weeks of treatment with prolonged exposure plus either the selective serotonin reuptake inhibitor (SSRI) paroxetine (n=19) or placebo (n=18). The experimental arm was more efficacious and deserves additional study. Results have been published.

World Trade Center evacuation study. PI: Robyn Gershon (Columbia University). The WTC Evacuation Study was a three-year study to improve understanding of individual, organizational, and environmental factors that helped or hindered evacuation from WTC Towers 1 and 2. Survivors recruited from Registry and other sources participated in in-depth interviews (n=30) or focus groups (5 groups of 4 survivors each), providing qualitative data that were transcribed and analyzed. This study has produced multiple publications.

High-Rise Evacuation Evaluation Database (HEED). PI: Ed Galea (University of Greenwich). Project HEED, which ended in 2008, which was funded by the UK Engineering and Physical Sciences Research Council, was collaboration among the Universities of Greenwich, Ulster, and Liverpool to investigate human behavior associated with evacuation of high rise buildings. Face to face interviews with 300 WTC survivors, facilitated by the Registry, were transcribed and analyzed to identify and quantify key issues that influence building evacuation. Simulation modeling of the North Tower evacuation has helped created and refine behavior algorithms to guide evacuation planning.

Functional neuroimaging of post-traumatic stress responses to 9/11. PIs: David Silbersweig (Brigham & Women's Hospital), James Root (Weill Cornell Medical School and Memorial Sloan Kettering Cancer Center). The study examined the regional brain activation in relation to emotional responses to the 9/11 WTC attacks, including both individuals who were directly exposed to the attack as well as individuals who were indirectly exposed/distant from the attack. Data collection is complete. Processing and analysis of functional and structural MRI data is under way. A manuscript is planned to be submitted in the late Spring of 2012.

WTC Responders Fatality Investigation Program: PI: K Gelberg (NYS DOH). A NIOSH funded study to identify deaths in rescue/recovery workers. Results have been published.

Headaches among Registrants in the Registry. PI: K Henry (NYU SOM and Bellevue Hospital). Registry PI: J Cone. A study of the relationship between headache, depression and PTSD among enrollees with reported concussion showed that headache is the most common symptom after mild head injury, and may persist for several years. Results have been published in abstract form.

Registry Presentations to Scientific Conferences and Workshops, Academic Institutions or Hospitals, Community Groups, and other Organizations

The Registry has participated actively with the WTCHP Centers of Excellence in recent forums and presentations of research results, and has hosted presentations from these programs at Registry Research Roundtables, including from scientists from Mt. Sinai, Bellevue and FDNY.

During the grant Years 01-03, Registry staff or collaborators presented findings at scientific conferences and workshops (n=39 presentations or posters), NYCDOHMH Epidemiology Grand Rounds (n=8), academic institutions (n=4), medical schools or hospitals, including Mt. Sinai (n=8), NYC

City Hall (n=3), and local health departments, community boards, and other local organizations (n=6). See *Section 2G: Presentations* for a list of presentations by Registry staff.

Education and Training: During the past three years, the Registry has continued to serve as a platform for public health training including:

Research Round Tables: The Registry has hosted over 45 research round tables for Registry research staff and visitors. These have included presentations of preliminary Registry findings; 9/-11 and related topics by outside researchers, including from the WTC Health Program; methods; and discussion of journal articles.

Public Health Training: The Registry has utilized the excellent infrastructure available through the DOHMH's Bureau of Public Health Training, including the Health Research Training Program (HRTP) and the Preventive Medicine Training Program. The Registry has provided a mentored research environment to a medical pediatric resident from Mt. Sinai School of Medicine (funded by Mt. Sinai; M Mann, MD), and twelve graduate and undergraduate HRTP interns and seven college aides (all funded by the NIOSH cooperative agreement)**.** Seven of the HTPR interns went on to complete their MPH theses by analysis of Registry data.

The pediatric resident is the lead author of a study that examined the effect of parental WTC-related PTSD on adolescent mental health and behavior. The HRTP interns/college aides were assigned to complete projects in the Treatment Referral Program, and the Medical Surveillance, Research/Survey, and Panel Maintenance Units, including the masters-related thesis analyses listed below. Other activities included: conducting GIS analyses; SAS programming; data preparation, recoding, analysis and QC; Wave 3 survey paper processing; assisting in preparing a Wave 3 codebook; enrollee tracing; and assisting with literature reviews.

Degrees completed during Years 01-03: Three full-time research staff completed PhD dissertations (AE Welch, A Pulizzi, and C Ekenga). Two of these doctoral dissertations focused on 9/11-related topics using Registry data: alcohol use and PTSD among residents (Welch) and construction of an exposure matrix for rescue/recovery workers (Ekenga). Ten Registry staff completed their Master's degrees, including three full-time staff (D Brown-Archat, MS; S Miller-Archie, MPH; and K Nelson, MBA) and seven graduate HRTP interns/college aides (A Kravitt, MPH; L Silverstein, MPH; K Caramanica, MPH; M Huang, MPH; S Mohajeri, MPH; H Waechter, MPH; and S Dziekan, MS). All of the HRTP interns/college aides master's degrees were based on analysis of Registry data: social support and mental health outcomes among residents (Waechter); privacy issues related to GIS representation of residential addresses (Dziekan); head injury and PTSD (Mohajeri); skin rash and 9/11 exposure (Huang); traumatic loss and long-term mental health outcomes (Caramanica); a case-control study of thyroid cancer among adults exposed to 9/11 (Silverstein); and birth outcomes of women exposed to the WTC disaster (Kravitt). The skin rash analysis has recently been published, and other thesis analyses have been integrated into publications by senior staff. Three of the interns have been hired into full-time NYCDOHMH positions (Waechter, Caramanica) and the Northern Manhattan Perinatal Partnership (Warren-Kigenyi). See *Section 2F: Publications* for a list of theses.

Other Training: Seven senior and eight junior research staff completed 37 SAS training courses over the past three years, and our IT/systems manager completed a software lifecycle development course. All but one of these senior staff, and 4 of the junior staff, utilized their SAS training to complete analyses that resulted in at least one manuscript in Years 01-03. Other staff applied their SAS training to enhance their programming skills in survival analysis using the proportional hazards model; categorical data analysis using logistic regression; macros; and ANOVA, OLS regression and logistic regression.

AIM 3: Conduct community activities to respond to the health concerns and specific needs of enrollees and others exposed to 9/11

Aim 3a: Disseminate Registry findings and recommendations to enrollees, the public and policy makers

Registry Advisory Committees: The Registry met regularly with our scientific advisory committee (SAC), community advisory board (CAB), and labor advisory committee (LAC) to provide updates on Registry findings and solicit feedback and advice.

9-11 Health Info website: Since 2009, www.nyc.gov/9-11HealthInfo has received ~ 4,300 unique visitors each month seeking the latest, comprehensive information about WTC-related services and research. In conjunction with the 9/11 health website, the WTC Health Coordinator publishes bimonthly a 9/11 health electronic newsletter. The newsletter is distributed to over 9,000 subscribers (including many Registry enrollees); a 42% increase in subscriptions since 2009.

The 9-11 Health Info website also includes the annual reports from the World Trade Center (WTC) Medical Working Group (MWG) and updates from the WTC Health Registry.

Communications with Enrollees and the Public: Dissemination channels for key communication activities with enrollees and the public varied by target audience and mode and included the following (in addition to the communications listed in Section 2, Results, Aim 1 above):

- The *Clinical Guidelines for Children and Adolescents Exposed to the WTC Disaster* was published by NYC DOHMH as a City Health Information booklet in July 2009. It was distributed to over 25,000 clinicians practicing in New York City, and posted on the 9/11 Health Information website.
- Co-chaired a WTC Health Forum with the WTC Environmental Health Center (EHC), *Surviving and Thriving after 9/11: Addressing the Health Impact of 9/11 on the Community*; Sept 16, 2010; at the City University of New York, NY, NY. The objective was to inform eligible populations, including enrollees and their families about treatment for WTC-related health conditions available at the WTC EHC at no out-of-pocket cost for eligible persons
- Sent postcard/email invitations to the WTC Health Forum to ~50,000 non-rescue/recovery enrollees.
- Created and sent bimonthly 9/11-related e-newsletters to enrollees and other subscribers.
- Provided 311 (the NYC government information phone number and web site) with the Registry updates.
- Disseminated 6 NYCDOHMH press releases which generated extensive print, television and radio coverage for key Registry publications and the Wave 3 survey, and 3 press releases to announce the NYC WTC MWG annual reports of 9/11 findings.
- Disseminated recruitment materials for approved external researchers as needed
- In-person communications with enrollees and the public (e.g., at resource fairs, community presentations)
- Disseminated 9/11-related health information and tobacco cessation information (details in Section 2, Results, Aim 3e below)

Numerous presentations were made to community boards, organizations, steering committees and hospitals regarding the Wave 3 survey, Registry findings, and 9/11 health resources (see *Section 2G: Presentations*).

Aim 3b: Inform enrollees of 9/11-related services, resources, and health promotion programs

The many ways we implemented this aim are described in Section 2, Results, Aims 3a and 3e.

Aim 3c: Develop and provide Registry data resources for, and respond to inquiries from, for enrollees and the public

An interactive health query data tool, the 9/11 Health Online Data Tool, available at the " 9-11 health info" website, was developed in 2009 and permits users to examine de-identified baseline survey data by crossing any two demographic, eligibility group, exposure, health condition, or rescue and recovery organization or agency variables. Since 2009, this data tool has been accessed nearly 2,000 times by users outside NYCDOHMH. This tool will be updated with Wave 2 data in 2012.

Aim 3d: Develop and disseminate updated 9/11-related treatment guidelines for physicians and other providers

The *Clinical Guidelines for Children and Adolescents Exposed to the WTC Disaster* was published by NYC DOHMH as a City Health Information booklet in July 2009. Although there have been many articles since the publication of the WTC clinical guidelines for treatment of adults (2008) and children and adolescents (2009), these guidelines remain clinically relevant and valuable.

Aim 3e: Offer healthcare referrals to enrollees with identified healthcare needs

The Tobacco Cessation Project: Through this project, we provided no-cost NRT kits and smoking cessation services to over 700 Registry enrollees and/or their household members. Pending analysis of Wave 3 questions on tobacco use, we continue to provide cessation services to enrollees who self-refer or who are identified through other Registry activities. Project evaluation is in progress; preliminary findings from a 6-month follow-up found that among those reached for follow-up (~49%), more than half (62%) had either quit or reduced the number of cigarettes smoked per day. We are in the process of identifying current smokers from Wave 3 to include in the next project.

The 9/11 Treatment Referral Program (TRP): TRP staff conducted personalized outreach to ~7,500 English language adult enrollees residing in NYC who reported physical or mental health symptoms or conditions on the Registry's Wave 1 or Wave 2 surveys, and were potentially eligible for HHC's WTC EHC SP. TRP staff also conducted outreach to ~1,000 parents/ guardians of all pediatric enrollees residing in NYC.

From Sept. 2009 through 2011, nearly 1,100 enrollees scheduled a first-time appointment at EHC as a result of TRP outreach, either through contact with TRP staff who scheduled the appointment (n=601) or by contacting EHC on their own (n=496). TRP was a major source of first-time appointments scheduled at the EHC during this time period. TRP also made appointments for enrollees (n=55) at other WTCHP sites.

In 2010, we conducted six focus groups to gain insights directly from enrollee survivors. The focus groups with enrollee revealed numerous barriers to care: lack of knowledge about 9/11-related conditions and services, difficulty accessing services, conflicting personal obligations, mental health stigma, and fear of treatment. Many expressed reluctance to utilize services that were not endorsed by their personal physicians and difficulty discerning whether their current medical conditions were related to 9/11. This qualitative research helped TRP staff address barriers to care, and was shared with

NIOSH, the WTCHP and community advisors. A manuscript summarizing these barriers to care is currently undergoing peer review at BMC Public Health.

Preliminary findings from our 6-12 month follow-up evaluation indicate that ~32% of enrollees with direct TRP contact scheduled an appointment at EHC and most (80%) reported having kept their appointment. Enrollees with physical ailments and PTSD, non-specific psychological distress or self-reported poor mental or physical health were more likely to make an appointment than those with physical health conditions only. Analysis is in progress.

Under the Zadroga Act, the Responder and Survivor programs are now under the federal WTCHP, effective July 1, 2011. Enrollees targeted for TRP outreach now receive a WTCHP application to submit on their own. TRP staff continues to assist with completing the form and answer questions about enrollment, eligibility and documentation and continue to coordinate closely with EHC. To date, over 575 survivor and responder enrollees have been sent a WTCHP application.

TRP has also been providing comprehensive and timely follow-up to address health problems, concerns and questions reported by enrollees on the Wave 3 survey, including distress during the telephone interviews. Follow-up includes a personalized letter and the WTCHP application or a phone call as appropriate.

To prepare for a planned expansion of TRP to include outreach to enrollee responders eligible for the WTCHP, a pilot mailing with the WTCHP application was sent to ~500 enrollee responders who reported physical health symptoms on the Wave 3 survey. The pilot has yielded 126 contacts to-date.

E. Conclusions

During the three year period of this cooperative agreement, the Registry has made a substantial contribution to the scientific literature on 9/11-related adverse health outcomes through the publication of 23 peer-reviewed manuscripts and the submission of an additional 3 manuscripts, including early cancer and mortality incidence studies that employed both internal and external comparisons.

The Registry has also initiated collaborations with NIOSH-funded WTC Centers of Excellence in NYC related to cancer assessment, investigations of potentially emerging health conditions, and lung function of symptomatic residents and office workers. Notably, Registry findings complement findings from the WTC Health Program and provide a more comprehensive understanding of 9/11 health impacts. The Registry has maintained a strong commitment to public health training, providing a mentored research environment to a medical pediatric resident from Mt. Sinai School of Medicine (funded by Mt. Sinai; M Mann, MD), and twelve graduate and undergraduate HRTP interns and seven college aides. In the past three years, two PhD theses and eight master’s level theses have been completed by staff and interns using Registry data.

The high degree of enrollee participation in Registry activities to date bodes well for the long-term viability of the Registry as a resource for researchers, policy makers and the public. The Registry launched pediatric and adult Wave 3 surveys to all enrollees and completed the adult survey. More than 63% of all adult enrollees participated in the 2011-12 Wave 3 survey (including nearly 78% of Wave 2 participants); similar response rates were obtained for Registry in-depth studies.

The Registry has also informed clinical practice by publishing studies on a range of health outcomes, emerging conditions and risk factors across diverse exposed populations, as well as unmet health care needs, and barriers to 9/11-related healthcare. We collaborated with the clinical WTC Centers of

Excellence and NYCDOHMH experts to develop clinical guidelines for physicians caring for children exposed to 9/11 to supplement the previously released adult clinical guidelines.

The Registry regularly translated its findings into public documents and recommendations for health care providers. Registry findings are widely disseminated through NYC DOHMH's 9/11HealthInfo website, e-newsletters, press releases, an annual report, and the annual reports of the NYC WTC Medical Working Group.

Registry research has implications for improved worker safety. Recommendations from Registry published findings include: the importance of respiratory protection for rescue/recovery workers and volunteers, the increased vulnerability of uniformed and volunteer workers assigned to rescue/recovery tasks without sufficient training and/or exposed to novel hazardous environments, and the increased vulnerability of already stressed populations (e.g., lower socioeconomic status or educational level, undocumented workers) to traumatic events.

Registry research has informed healthcare policy. Our published estimates of the burden of 9/11 health impacts in affected populations and information on unmet care needs have been shared with city and federal officials, justifying the need for extended healthcare services for survivors and responders via the WTC Health Program established under the Zadroga 9/11 Health and Compensation Act of 2010.

The Registry also facilitated collaborative and independent studies by U.S. and international academic researchers by providing de-identified data and cost-efficient access to enrollee subgroups for recruitment that has provided recommendations for: improvements to evacuations from high rise buildings, reducing the impact PTSD among first responders has on their children, and identification of organizational and behavioral barriers to rapid and efficient evacuation of buildings in a disaster.

F. **Publications**

Journal Articles

Antao VC, Pallos LL, Shim YK, Sapp JH 2nd, Brackbill RM, Cone JE, Stellman SD, Farfel MR: [2011] Respiratory protective equipment, mask use, and respiratory outcomes among World Trade Center rescue and recovery workers. American Journal of Industrial Medicine 54(12):897-905.

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Brackbill RM, Hadler JL, DiGrande L, Ekenga CC, Farfel MR, Friedman S, Perlman SE, Stellman SD, Walker DJ, Wu D, Yu S, Thorpe LE: [2009] Asthma and posttraumatic stress symptoms 5 to 6 years following exposure to the World Trade Center terrorist attack. The Journal of the American Medical Association 302(5):502-516.

Brackbill RM, Stellman SD, Farfel MR: [2012] Unmet mental health care needs among survivors of the September 11, 2001 World Trade Center Disaster. Social Science & Medicine, submitted.

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Ekenga CC, Scheu KE, Cone JE, Stellman SD, Farfel MR: [2011] 9/11-related experiences and tasks of landfill and barge workers: qualitative analysis from the World Trade Center Health Registry. BMC Public Health 11(1):321.

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Huang MJ, Li J, Liff JM, Cohen DE, Cone J: [2012] Self-reported skin rash or irritation symptoms among World Trade Center Health Registry participants. Journal of Occupational and Environmental Medicine 54(4):451-458.

Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD: [2011] Mortality among survivors of the Sept 11, 2001, World Trade Center disaster: results from the World Trade Center Health Registry cohort. Lancet 378(9794):879-887.

Jordan HT, Miller SA, Cone JE, Morabia A, Stellman SD: [2012] The authors respond. Preventive Medicine 54(5):365.

Jordan HT, Miller-Archie SA, Cone JE, Morabia A, Stellman SD: [2011] Heart disease among adults exposed to the September 11, 2001 World Trade Center disaster: results from the World Trade Center Health Registry. Preventive Medicine 53(6):370-376.

Jordan HT, Osahan SS, Cone J, Stellman SD, Prezant DJ: [2012] Authors' Response. Journal of Occupational and Environmental Medicine 54(1):2-3.

Jordan HT, Stellman SD, Prezant D, Teirstein A, Osahan SS, Cone JE: [2011] Sarcoidosis diagnosed after September 11, 2001, among adults exposed to the World Trade Center disaster. Journal of Occupational and Environmental Medicine 53(9):966-974.

Li J, Brackbill RM, Stellman SD, Farfel MR, Miller-Archie SA, Friedman S, Walker DJ, Thorpe LE, Cone J: [2011] Gastroesophageal reflux symptoms and comorbid asthma and posttraumatic stress disorder following the 9/11 terrorist attacks on World Trade Center in New York City. The American Journal of Gastroenterology 106(11):1933-1941.

Li J, Cone J, Brackbill R, Farfel M, Greene CM, Stellman SD: [2012] Cancer incidence in the World Trade Center Health Registry cohort, 2003-2008. The Journal of the American Medical Association, submitted.

Lipkind HS, Curry AE, Huynh M, Thorpe LE, Matte T: [2010] Birth outcomes among offspring of women exposed to the September 11, 2001, terrorist attacks. Obstetrics & Gynecology 116(4):917-925.

Maslow CB, Friedman SM, Pillai PS, Reibman J, Berger KI, Goldring R, Stellman SD, Farfel M: [2012] Chronic and acute exposures to the world trade center disaster and lower respiratory symptoms: area residents and workers. The American Journal of Public Health 102(6):1186-1194.

Nair HP, Ekenga CC, Cone JE, Brackbill RM, Farfel MR, Stellman SD: [2012] Co-occurring Lower Respiratory Symptoms and Posttraumatic Stress Disorder 5 to 6 Years After the World Trade Center Terrorist Attack. The American Journal of Public Health 102(10):1964-1973.

Perlman SE, Friedman S, Galea S, Nair HP, Eros-Sarnyai M, Stellman SD, Hon J, Greene CM: [2011] Short-term and medium-term health effects of 9/11. Lancet 378(9794):925-934.

Stellman SD, Thomas PA, Osahan SS, Brackbill RM, Farfel MR: [2012] Respiratory health of 985 children exposed to the World Trade Center disaster: World Trade Center Health Registry Wave 2 follow-up, 2007-2008. Journal of Asthma, submitted.

Thorpe LE, Friedman S: [2011] Health consequences of the World Trade Center disaster: a 10th anniversary perspective. The Journal of the American Medical Association 306(10):1133-1134.

Welch AE, Caramanica K, Debchoudhury I, Pulizzi A, Farfel MR, Stellman SD, Cone JE: [2012] A qualitative examination of health and health care utilization after the September 11th terror attacks among World Trade Center Health Registry enrollees. BMC Public Health 12(1):712-721.

Book Chapters

Weisfuse IB, Marsik T, Brackbill RM: [2011] The Public Health Response to the World Trade Center Attack and Its Aftermath by the New York City Department of Health and Mental Hygiene. In: Terrorism and Public Health 2nd ed., (eds. BS Levy, VW Sidel), Oxford University Press, pp 43-66.

Dissertation/Thesis

Afshar N: [2012] WTCHR Cares: A Description and Analysis of Smokers Enrolled in a Tobacco Cessation Program, 2008-2010, MPH Thesis, Hunter College.

Caramanica K: [2011] Traumatic Loss and Long-Term Mental Health Outcomes Among WTC Health Registry Enrollees, MPH Thesis, Mailman School of Public Health, Columbia University.

Dziekan S: [2010] Context sensitive geographic masks: implementations and evaluations of random perturbation for the protection of confidential spatial data in densely populated areas, MS Thesis, Hunter College.

Ekenga C: [2011] Respiratory Health Outcomes among WTC Disaster Workers Five to Seven Years after September 11, 2001, PhD Dissertation, New York University.

Huang M: [2010] Self-Reported Skin Rash or Irritation Symptoms Among WTC Health Registry Participants, MPH Thesis, Rollins School of Public Health, Emory University.

Kravitt A: [2012] Birth Outcomes Among Pregnant Women Exposed to the WTC Attacks on September 11, 2001, MPH Thesis, Mailman School of Public Health, Columbia University.

Mohajeri S: [2010] The relationship between head injury and posttraumatic stress disorder among those present South of Chambers Street in Manhattan during the World Trade Center terrorist attacks of September 11, 2001, MPH Thesis, Mailman School of Public Health, Columbia University.

Silverstein L: [2012] Nested Case-Control Study of Thyroid Cancer in the WTC Health Registry Cohort, MPH Thesis, Mailman School of Public Health, Columbia University.

Waechter H: [2009] Social Support and Mental Health Outcomes in Lower Manhattan Residents 5-6 Years Following the September 11, 2001 Attacks, MPH Thesis, Mailman School of Public Health, Columbia University.

Welch AE: [2010] The Effects of 9/11-Related Postraumatic Stress Disorder on Problem Alcohol Use Among WTC Health Registry Enrollees, DrPH Dissertation, School of Public Health, City University of New York.

G. Presentations

WTC HEALTH REGISTRY PRESENTATIONS - (April 30, 2009 TO JULY 8, 2012)

PRESENTATIONS AT CONFERENCES			
DATE	**PRESENTER(S) / AUTHOR(S)**	**TITLE**	**LOCATION**
5/20/2009	Ekenga C, Stellman S, Fung L, Friedman S, Maslow C, Cone J.	Reactive airways dysfunction syndrome (RADS) among rescue and recovery workers in the Registry	American Thoracic Society, San Diego, CA.
9/10/2009	Brackbill R, Welch A, DiGrande L.	PTSD surveillance and treatment referral using the WTCHR.	CDC's Biennial Mental Health Surveillance Meeting, Atlanta, GA
9/13/2009	SD Stellman, AE Welch, J Cone, M Farfel, LE Thorpe	From Research to Action: Active Referral in the World Trade Center Health Registry	Annual meeting of the American College of Epidemiology, Silver Spring, MD
10/26/2009	Bowler R, Han H, Nakagawa S, DiGrande L, Cone J Presented by R Brackbill	Gender Differences in Post Traumatic Stress Disorder among Police Officers who Responded to the 2001 World Trade Center Terrorist Attack	CDC Environmental Health Conference, Atlanta, GA
10/26/2009	Brackbill R, Shim Y, Sukhminder O, Stellman S.	Current Health Status of Persons Injured in the September 11, 2001 Terrorist Attacks	National Environmental Public Health Conference, Atlanta, GA,
10/26/2009	Brackbill R, Hadler JL, Ekenga C, Farfel M, Friedman S, Stellman S, Thorpe L,	Diagnosed Asthma Among Persons Exposed to the September 11, 2001 Terrorist Attacks	National Environmental Public Health Conference, Atlanta, GA,
11/6/2009	Brackbill R, DiGrande L, Stellman S,	Posttraumatic stress symptoms 5 to 6 years following exposure to the World Trade Center terrorist attack.	Presented at the 8th International Conference on Occupational Stress and Health, San Juan, PR.
11/11/2009	SD Stellman, RM Brackbill, JL Hadler, CC Ekenga, MR Farfel, S. Friedman, LE Thorpe	Diagnosed Asthma Among Persons Exposed to the September 11, 2001 Terrorist Attacks	Annual meeting of the American Public Health Association, Philadelphia, PA
11/11/2009	J Cone	Presided over APHA Panel: Health of Workers Exposed to the September 11, 2001 World Trade Center disaster, eight years later.	Annual meeting of the American Public Health Association, Philadelphia, PA
11/11/2009	RM Brackbill, Y Shim, O Sukhminder, Steve Stellman	Current Health Status of Persons Injured in the September 11, 2001 Terrorist Attacks	Annual meeting of the American Public Health Association, Philadelphia, PA
7/23/2010	J Cone	World Trade Center Health Registry - A Model for a Nanomaterials Exposure Registry	Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research, Keystone Conference Center, Keystone, CO
9/23/2010	J Cone	World Trade Center Health Registry - A Model for a Gulf Oil Spill Exposure Registry?	National Academy of Sciences, Oil Spill Workshop 1. Grand Hyatt, Tampa, FL
10/1/2010	AE Welch, D Hasin, L Borrell, JE Cone, SD Stellman, MR Farfel	Problem Drinking Among Adult Enrollees in the WTC Health Registry	Poster presentation, American Public Health Association, Annual Meeting, Denver, CO

10/29/2010	C Ekenga, K Scheu, J Cone, SD Stellman, M Farfel	A Qualitative Analysis of the 9/11 Related Experiences of World Trade Center Recovery and Clean-up Workers	Poster presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	C. Maslow, J. Li, H. Jordan, H. Nair, I. Debchoudhury, C. Ekenga	Acute and Chronic Exposures to the Events of 9/11 and Lower Respiratory Symptoms: WTC Area Residents and Workers	Paper presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	J Li, RM Brackbill, SD Stellman, MR Farfel, S Miller, S Friedman, DJ Walker LE Thorpe, J Cone	Gastroesophageal Reflux Symptoms Among WTC Health Registry Enrollees Exposed to the 9/11 disaster	Paper presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	HT Jordan, SD Stellman, DJ Prezant, J Cone,	Sarcoidosis Diagnosed After September 11, 2001 Among Persons Exposed to the World Trade Center disaster.	Paper presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	HP Nair, C Ekenga, C Maslow, R Brackbill, L DiGrande, J Cone, M Farfel, SD Stellman	Risk Factors and Quality of Life Associated with Persistent Respiratory and Co-morbid Posttraumatic Stress Symptoms 5-6 Years After the World Trade Center Terrorist Attack	Paper presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	I. Debchoudhury, A Welch, M Fairclough, JE Cone, RM Brackbill, SD Stellman, MR Farfel	Mental Health Outcomes Among Rescue and Recovery Volunteers in the World Trade Center Health Registry.	Paper presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
10/29/2010	AE Welch, J Fields, O Harel, D Wallingford, JE Cone, M Farfel	The 9/11 Treatment Referral Program: An Inter-Agency Collaboration to Promote the Health of WTC Health Registry Enrollees Residing in NYC	Poster presented at the Ninth International Conference on Urban Health, NY Academy of Medicine, NY, NY
3/25/2011	SD Stellman (accepted presentation)	PTSD and it correlates among enrollees of the WTC Health Registry	Anxiety Disorders Association of America (ADAA), New Orleans, LA
6/1/2011	R Zeig-Owens, J Cone	Defining cancer outcomes among four cohorts of rescue/recovery workers who responded to the World Trade Center disaster	Council of State and Territorial Epidemiologists Annual Meeting, Pittsburgh, PA
6/1/2011	J Weakley, C Maslow	Defining Common Categories of Exposure among Four Cohorts of Rescue/Recovery Workers who Responded to the World Trade Center Disaster	Council of State and Territorial Epidemiologists Annual Meeting, Pitsburgh, PA
6/22/2011	R. Brackbill	Unmet Mental Health Care Needs Among WTC Disaster Survivors	3rd North American Congress of Epidemiology, Montreal, Quebec, Canada
10/13/11	J. Cone	Mortality Among Survivors of the 9/11 WTC Disaster	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/13/11	S. Friedman	Case-Control Study of Lung Function in World Trade Center Health Registry Area Residents and Workers	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY

10/13/11	R. Bowler	Longitudinal Mental Health Impact Among Police Respondents to the 9/11 Terrorist Attack	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/13/11	R. Brackbill	Unmet Mental Health Care Needs Among World Trade Center (WTC) Disaster Survivors	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/13/11	R. Brackbill	Asthma Prevalence and Severity, and Health Related Quality of Life Associated With Asthma, Among 9/11 Rescue and Recovery Workers with and Without PTSD	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/13/11	S. Miller	Heart Disease Among Adults Exposed to the September 11, 2001 WTC Disaster: Results From the WTC Health Registry	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway
10/13/11	M. Mann	Parental PTSD Increases the Risk of Impaired Behavior and PTSD in Adolescents 6-7 years after the 9/11 Disaster	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/13/11	S. Stellman, S. Osahan	Respiratory Health of Children Enrolled in the World Trade Center Health Registry, 6 Years Following 9/11/01.	Joint Conference on Health Impact of 9/11: The First Decade, United Federation of Teachers, 52 Broadway, NY, NY
10/29/11	I. Debchoudhury	Comparison of Health Outcomes Among Affiliated and Lay Disaster Volunteers Enrolled in the World Trade Center Health Registry	Poster Presentation, Annual Public Health Association Conference
5/5/12	N. Afshar	The World Trade Center Health Registry Cares: An Assesment of Outcomes from a Tobacco Cessation Program, 2008-2010.	PHANYC 7th Annual Student Conference NYU Langone Medical Center, NY, NY
5/17/12	S. Yu	Survey Mode Preference Among Enrollees in the World Trade Center Health Registry	Poster Presentation, American Association for Public Opinion Research(AAPOR) 67th Annual Conference, Orlando, FL
5/18/12	J. Murphy, R. Brackbill, S. Yu, D. Wu, D. Walker, L. Turner, S. Stellman, S. Miller, E. Saleska	Disentangling Mode and Nonresponse Effects in the World Trade Center Health Registry	American Association for Public Opinion 67th Annual Conference, Orlando, FL
5/23/12	V. Antao	Respiratory Health Outcomes and Home Conditions of Lower Manhattan Residents Enrolled in the World Trade Center Health Registry	Poster Presentation, 2012 ATS International Conference in San Francisco, CA
6/5/12	J. Li	Self-reported skin rash or irritation symptoms among WTCHR participants.	Poster Presentation, 2012 Council of State and Territorial Epidemiologists Annual Conference, Omaha, NE
6/5/12	A. Welch	A qualitative examination of health and health care utilization after the September 11, 2001 terror attacks among World Trade Center Health Registry enrollees	2012 Coucil of State and Territorial Epidemiologists Annual Conference, Omaha, NE

PRESENTATIONS IN THE COMMUNITY

10/4/2010	J Hon	Findings from the 2010 WTC Medical Working Group Annual Report	Manhattan Community Board 1, WTC Redevelopment Committee Meeting , NY, NY
7/13/2011	M. Farfel	Introduction to the WTC Health Registry	Presentation to the September 11th Victims Compendation Fund Special Master, NY, NY

OTHER PRESENTATIONS

DATE	PRESENTER(S) / AUTHOR(S)	TITLE	LOCATION
5/29/2009	Stellman, SD	Opportunities for external researchers	Department of Epidemiology Faculty Meeting, Columbia University, NY, NY
11/19/2009	M Farfel	Registry Overview, US Army War College Visitors	NYCDOHMH,125 Worth Street, New York, NY,
1/25/2010	J Cone	NYCDOHMH Presentations at APHA in 2009, Discussant at Epidemiology Grand Rounds.	Epidemiology Grand Rounds, NYC Department of Health,125 Worth Street, NY NY
1/29/2010	J Cone	Occupational Health Disparities	Grand Rounds at Mt. Sinai Occupational Medicine Rounds, Mt. Sinai Hospital, NY, NY
3/17/2010	M Farfel, S Stellman	Persistent Physical and Mental Health Effects in WTC Survivors	Columbia University Seminar on Injury Prevention and Control, NY, NY
4/1/2010	M. Farfel, S.Stellman	Mayor's World Trade Center Medical Working Group - Findings of the Cancer Study.	NYC City Hall - In the Committee of the Whole (COW) Room, NY, NY
4/30/2010	SD Stellman	Persistent Physical and Mental Health Effects in World Trade Center Survivors	Clinical Seminar Series, Mt. Sinai School of Medicine, NY, NY
5/21/2010	SD Stellman	Psychological Outcomes in World Trade Center Health Registry Studies	Clinical Seminar Series, Mt. Sinai School of Medicine, NY, NY
8/5/2010	M. Farfel, S.Stellman	Mayor's World Trade Center Medical Working Group - Preliminary Findings of the Mortality Study	City Hall - In the Committee of the Whole (COW) room, NY, NY
8/30/2010	S. Friedman	A Community Based Case Control Study of Respiratory Symptoms and Lung Function Among Lower Manhattan Residents and Area Workers Enrolled in the World Trade Center Health Registry	Epidemiology Grand Rounds, New York City Department of Health, 125 Worth Street, NY, NY
8/30/2010	I. Debchoudhury	Mental and Physical Health Outcomes Among Volunteers Enrolled in the World Trade Center Health Registry	Epidemiology Grant Rounds, New York City Department of Health, 125 Worth Street, NY, NY
8/30/2010	J. LI	Gastro-esophageal Reflux Symptoms (GERS) Among Persons Exposed to the 9/11 Disaster	Epidemiology Grand Rounds, New York City Department of Health, 125 Worth Street, NY, NY
9/9/2010	J. Cone	Long Term Health Effects of 9/11	Richmond County Medical Center, Staten Island, NY

9/15/2010	AE Welch	The World Trade Center Health Registry 9/11 Treatment Referral Program: A Partnership with the WTC Environmental Health Center	Surviving and Thriving After 9/11: Addressing the health impact of 9/11 on the Community, The CUNY Graduate Center, 365 Fifth Avenue, NY, NY
9/27/2010	M. Farfel, S.Stellman,	Data Sharing From the World Trade Center Health Registry	Epidemiology Grand Rounds, New York City Department of Health, 125 Worth Street, NY, NY
12/9/2010	J Cone	Progress of WTC Analytic Methods Workgroup	Mayor's WTC Medical Working Group, City Hall, NY, NY
1/10/2011	SD Stellman	Persistent Physical and Mental Health Effects in World Trade Center Survivors	Harvard School of Public Health, Harvard Education and Research Center (ERC), Boston, MA
3/15/2011	S. Stellman	Persistent Physical and Mental Health Effects in World Trade Center Survivors.	Public Health and Preventive Medicine Grand Rounds, UMDNJ - New Jersey Medical School, Newark, NJ
5/13/2011	M. Farfel, J. Cone, R. Brackbill, S. Stellman,	World Trade Center Health Registry Findings	Chronic Disease Cluster Seminar, Mailman School of Public Health, Columbia University, NY, NY
9/26/11	S. Stellman	Respiratory Outcomes in Children Exposed to the WTC Disaster	Division of Epidemiology Grand Rounds, 125 Worth Street, NY, NY
9/26/11	H. Jordan, S. Miller	Heart Disease (HD) among Adults Exposed to the September 11, 2001 World Trade Center Disaster: Results from the World Trade Center Health Registry.	Division of Epidemiology Grand Rounds, 125 Worth Street, NY, NY
9/26/11	M. Mann	Parental PTSD as a Risk Factor for Adolescent Behavioral Impairment and PTSD 6-7 years after the 9/11 Disaster	Division of Epidemiology Grand Rounds, 125 Worth Street, NY, NY
12/21/11	S. Friedman	Pulmonary Health Effects of 9/11	SUNY Downstate Medical Resident Pulmonary Rounds, Brooklyn, NY
1/27/12	J. Cone	Observational Studies	Mt. Sinai Occupational Medicine and Preventive Medicine Residents Lecture, NY, NY
3/21/12	J. Cone	WTCHR Study Results, 9/11 Related Exposure	Stony Brook Medical School Course, Stony Brook, NY
6/21/12	S. Friedman	Pulmonary Health Effects of the World Trade Center Disaster	American College of Physicians, New York Chapter Brooklyn District Meeting, Brooklyn, NY
6/22/12	S. Friedman	Pulmonary Health Effects of the WTC Disaster	Brooklyn Internal Medicine Physicians Group, Brooklyn, NY

H. Selected Publications/Presentations by External Researchers

Galea ER, Sharp G, Lawrence PJ, Holden R. Approximating the evacuation of the World Trade Center North Tower using Computer Simulation. *Journal of Fire Protection Engineering.* 2008;18(2):85-115.

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I. Inclusion Enrollment Report (from our original NIOSH proposal March 09)

Study Title: World Trade Center Health Registry

Total Enrollment: 71,437 **Protocol** NYCDOHMH IRB protocol 02-058

Grant Number: 1U50OH009739 (CDC-NIOSH)

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled (Cumulative) by Ethnicity and Race

	Sex/Gender			
Ethnic Category	**Females**	**Males**	**Unknown or Not**	**Total**
Hispanic or Latino	4162	5176	0	9338 **
Not Hispanic or Latino	24005	36916	1	60922
Unknown (individuals not reporting ethnicity)	474	702	1	1177
Ethnic Category: Total of All Subjects*	28641	42794	2	71437 *
Racial Categories				
American Indian/Alaska Native	131	202	0	333
Asian	2443	2528	0	4971
Native Hawaiian or Other Pacific Islander	105	129	0	234
Black or African American	5097	3744	0	8841
White	16570	30888	1	47459
More Than One Race	1168	1318	0	2486
Unknown or Not Reported***	3127	3985	1	7113
Racial Categories: Total of All Subjects*	28641	42794	2	71437 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not**	**Total**
American Indian or Alaska Native	78	113	0	191
Asian	22	26	0	48
Native Hawaiian or Other Pacific Islander	26	30	0	56
Black or African American	327	322	0	649
White	1432	1978	0	3410
More Than One Race	293	349	0	642
Unknown or Not Reported***	1984	2358	0	4342
Racial Categories: Total of Hispanics or	4162	5176	0	9338 **

* These totals must agree.
** These totals must agree. ***Includes Others

J. Inclusion of gender and minority study subjects

This section was derived from our original 3 year NIOSH application in March 2009.

1. *The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. Describe the women and minority composition of the population base from whom the specimens and/or data will be obtained. (Include the Targeted/Planned Enrollment Table).*

The Registry cohort was established in 2003-04 when 71,437 persons voluntarily enrolled and completed the initial survey ("Wave 1 survey"). The Inclusion Enrollment Report (*Section I* above) describes the gender distribution overall (40% female overall) and by racial/ethnicity groups. The distribution of Registry enrollees by racial categories is as follows: White (n=47,459, 66.43%), Black (n=8,841, 12.37%), Asian (n=4,971, 6.85%); American Indian/Alaska native (n=131); Native Hawaiian or Other Pacific Islander (N=234), More than One Race (n=2,486, 3.45%) and Unknown or Not Reported (n=7,113, 9.96%). The distribution of enrollees by ethnic categories is as follows: Hispanic or Latino (n=9,338, 13.07%), Not Hispanic or Latino (n=60,922, 85.28%) and Unknown (n=1,177, 1.65%). The diversity of the enrollee cohort reflects in part the diversity of workers and residents in NYC and the tri-state area where ~90% of enrollees reside.

2. *A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.*

Not Applicable. The development of eligibility groups for the WTC Health Registry took into account proximity by time and place to the WTC attacks and likelihood of acute exposure to the immediate dust cloud that resulted from the collapse of the towers and ongoing exposures to dust, smoke and fumes in the vicinity of the WTC site. There were no selection criteria based on gender or racial/ ethnic group. The four broad eligibility groups described above in Section 2A: *Background* were created to include persons most likely to have had direct exposure to the events of 9/11and its aftermath.

3. *A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.*
Not Applicable. There were no exclusion criteria based on gender or racial/ethnic group at the time of the creation of the WTC Health Registry. In the proposed continuation of Registry research there will be no exclusions based on gender or racial/ethnicity group.

4. *A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.*
Outreach to eligibility groups, including under-represented subgroups of lower Manhattan residents and workers (e.g., Chinese and Spanish speaking residents and workers), occurred during the Wave 1 and 2 surveys and included outreach to residential buildings and individual enrollee homes. The latter also included outreach to the homes of parents/guardians of child enrollees (including Spanish and Chinese speaking parents/guardians) to encourage them to complete and return the surveys for their children. In addition, outreach during the Wave 1 survey included collaborations with community organizations (e.g., the Chinese Benevolent Association) to facilitate and encourage potential enrollees to enroll and outreach to work locations (with high percentages of under-represented racial/ethnic groups) in lower Manhattan.

Outreach was conducted during the Wave 3 survey to eligibility groups/subgroups (e.g., residential buildings, rescue/recovery workers), and to individuals (e.g., through targeted communications and home visits) to encourage enrollees to complete their Wave 3 survey. Examples of outreach to groups included staffing of informational tables at key locations; posters; flyers; advertisements or articles in lower Manhattan, Chinese and Spanish newspapers; student newsletters and websites; and rescue/recovery workers, newsletters, websites and newspapers. Additional intensive outreach to individuals, including home visits and telephone calls, is planned to boost response rates to Wave 3 among those subgroups that are under-represented among the respondents to Wave 3 at the time of outreach. Outreach to boost response rates to other special surveys will be conducted as needed.

None of the Registry studies excluded a gender or minority groups.

K. Inclusion of children (under the age of 21 years)

This section was derived from our original 3 year NIOSH application in March 2009.

We plan to include children in all areas of the proposed research, with the exception of the Staten Island and barge worker study (research activity #3) and the In-depth Respiratory studies (research activity #6) as explained below:

Research activity #1, “develop and conduct a 2nd follow up survey (“Wave 3 survey”) to ascertain the health status of enrollees ~10 years after 9/11” will include data collection from parents/guardians of adolescent enrollees (aged 11 to 17 years) and also directly from adolescents. Children who will have aged into adulthood (aged 18 to 21) by the time of the Wave 3 survey will be send the adult version of the Wave 3 survey. Thus, we will include all children up to 21 years of age in the Wave 3 survey. By the time the Wave 3 survey is launched, we expect to have sufficient numbers of children to contribute to a meaningful analysis, i.e., ~2,000 children under the age of 21 years, including ~1,340 children under the age of 18 years.

Research activity #2, “conduct follow-up investigation of potentially emerging conditions” will entail verification of self-reported cases of particular health conditions in both children and adults through medical record reviews and abstraction (and speaking with physicians) as well as potential follow-up case control studies when indicated.

Research activity #3, “conduct the Staten Island and barge worker study” will not include children because at this time there are no enrollees under the age of 21 who performed work at these sites as part of 9/11-related recovery operations.

Research activity #4, “complete and submit for publication a wide range of analyses using data from the Wave 1 (2003-04) and Wave 2 (2006-08) surveys” includes the analysis and reporting of data collected from parents/guardian proxies of child enrollees (for all children younger than 18 years of age during the Wave 1 and 2 surveys) and data collected directly from adolescent enrollees aged 11-17 years as part of the Wave 2 surveys, as well as data collected from individuals aged 18 to 21 years during both the Wave 1 and Wave 2 surveys).

Research activity #5, “complete the initial cancer and mortality assessments” entails the collection of additional data through periodic matches of the WTCHR database, including records on child enrollees, with NDI, the NYC Vital Statistics database, and 11 selected state cancer registries, and hospitalization records if needed.

Research activity #6, “complete the in-depth case control and case series studies of respiratory symptoms among adult residents and building workers in lower Manhattan” entails the collection of additional data on 9/11-exposures and post-9/11 symptoms through surveys, and clinical measures of pulmonary function tests (PFTs) (e.g., spirometry and oscillometry).

Research activity # 7, “facilitate independent and collaborative research by researchers at the WTC Centers of Excellence and elsewhere in academia and government through sharing Registry de-identified data” includes the dissemination of informational materials to parents/guardian proxies of child enrollees and to adult enrollees, including individuals aged 18 to 21 years. It should be noted that the research plan for children does not involve collaborating sites.

Expertise of the investigating team for working with children at the ages included

All the proposed research on children will be done at the office of the Registry or the offices of our survey contractor. Note that at this time (2009), the sub-cohort of child enrollees in the WTCHR is comprised of children who are least 8 years of age.

The Registry research team has members with experience in research involving children, including the collection and analysis of Registry Wave 1 and 2 survey data on children and adolescents in 2003-4 and 2007-8, respectively. Registry scientific advisors also have extensive pediatric expertise.

A SAC member since 2005, and pediatric consultant to the Registry since 2009, Pauline Thomas, MD, FAAP, is a board certified pediatrician with both clinical and research expertise in pediatrics and children's public health. Dr. Thomas has been a principal or co-investigator in numerous IRB approved projects involving children, including CDC funded epidemiologic studies of pediatric HIV and childhood immunizations, as well as the WTC Health Registry Wave 1 initial enrollment survey in 2003-2004. In her current role as Associate Professor of Preventive Medicine and Community Health at New Jersey Medical School, and Associate Professor at the UMDNJ School of Public Health. She has worked on evaluations of children enrolled in WIC, including patterns and rates of blood lead screening, evaluation of adequacy of primary care in Newark, and patterns of overweight in the children and their mothers. She has also participated in analysis of autism surveillance data in New Jersey, publishing on the association between autism and socioeconomic status. Dr. Thomas is familiar with and an expert in issues in child health, and protection of human subjects as it pertains to children. As a primary care pediatrician, she is aware of basic pediatric evaluation and care. Dr. Thomas maintains a part-time private pediatric practice with the Summit Medical Group in Berkeley Heights, New Jersey, and has clinical privileges at University Hospital in Newark, and at Overlook Hospital in Summit, NJ. She maintains her medical license in both New York State and New Jersey. As a member of the WTCHR's Scientific Advisory Committee (SAC) she consults as needed with other members on specialty topics including pulmonary health and child psychological disorders, and has provided input into the design of the Wave 2 survey for children and adolescents and co-authored the Registry's published manuscript on children's respiratory health based on the Wave 1 survey. Under this proposal, she will serve as a consultant to the Registry on matters pertaining to the inclusion of children in Registry research, including the design and content of the Wave 3 follow-up survey as well as the analysis of Wave 3 survey data on children.

The Registry's SAC also includes Dr. Christine Hoven, an expert on children's mental health, who has conducted and published her own research on children's mental health following the 9/11 disaster. Dr. Hoven is currently an approved WTCHR external researcher conducting a study on the impact of parents' trauma experiences on the mental health of their children. She will also provide input into the design and content of the Wave 3 survey of children. She plans to remain a SAC member and is interested in collaborating with the Registry on an external study of co-morbid respiratory and mental health conditions among enrollee children.

L. Materials available for other researchers

WTC Health Registry: Resource Sharing Plan

The Registry's plan for sharing research data includes two primary components:

1. **Public Use Research Data Resources:**
   The Registry will continue to maintain and update data resources and data sources for enrollees, the public and external researchers that are accessible via the Registry's web page on the nyv.gov/9-11HealthInfo website including: Waves 1-3 adult and pediatric surveys, a Wave 1 Data File User's Manual (DFUM), and an interactive health query data tool. The DFUM includes a codebook with frequencies of responses to Wave 1 variables. The responses have been collapsed to protect enrollee confidentiality.

   The interactive health data tool provides access to de-identified data (frequencies and cross-tabs) and permits users to access this data by running a query to obtain the cross of any two demographic variables, eligibility group (e.g., residents, rescue/recovery workers), exposures or health conditions, or the frequencies of any one of these variables. The current interactive health data tool displays data from the Wave 1 survey. Since 2009, this data tool has been accessed nearly 2,000 times by users outside NYCDOHMH.

   Registry staff have completed updates to this interactive health data tool that include incorporating some key Wave 2 health findings into the de-identified data so that users could query and retrieve this data. Pending is final quality control checks to ensure that these Wave 2 variables are sufficiently collapsed to ensure enrollees' confidentiality is protected.

   In Year 04, Registry staff will consult with Dr. Kevin Konty, Director of the Methodology Unit, Division of Epidemiology, NYCDOHMH, who is an expert in data masking to protect individual confidentiality, to seek his advice and guidance in conducting the final QC checks of the Wave 2 survey variables to be added to the interactive health data tool. (A small percentage of Dr. Konty's time is included in our PS justifications.) This updated interactive health data tool, along with the Wave 2 and Wave 3 Data File User's Manuals (DFUMs), including their codebooks, will be posted on the Registry's webpage in Year 04. (Note: Posting of the Wave 2 DFUM was delayed due to the same potential issues related to confidentiality as the Wave 2 updates to the interactive health data tool.)

   Research Data for External Researchers: We will continue our established process for reviewing requests from qualified external researchers for de-identified survey data and for disseminating approved recruitment materials to eligible enrollees. Staff will continue to run data queries for external researchers, policy makers, press, and others, and create de-identified data sets for approved external research projects. Considerable staff resources are invested in running data queries to help address research issues or inform policy and preparing data for external researchers.

   The protocol for External Researchers was revised in 2007 and approved by the NYCDOHMH IRB to permit release to an approved external researcher individual enrollee survey data upon our receipt of and verification of these enrollees' signed, notarized consent. In 2011, the first release of this data type occurred. We released Wave 1 and Wave 2 survey data for ~ 545 adult enrollees to Dr. Christina Hoven, Columbia University and NY State Psychiatric Institute, under her approved external research study which assesses child mental health status in relation to both child and parent WTC experiences.