A. OVERALL COVER PAGE

Project Title: Development and implementation of a comparison occupational cohort for the WTC GRC	
Grant Number: 5U01OH011487-03	**Project/Grant Period:** 07/01/2018 - 06/30/2021
Reporting Period: 07/01/2020 - 06/30/2021	**Requested Budget Period:** 07/01/2020 - 06/30/2021
Report Term Frequency: Final	**Date Submitted:** 08/25/2023
Program Director/Principal Investigator Information: SUSAN L TEITELBAUM , BS MPH PHD **Phone Number:** (212) 824-7105 **Email:** susan.teitelbaum@mssm.edu	**Recipient Organization:** ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI 1 GUSTAVE L. LEVY PL NEW YORK, NY 100296574 **DUNS:** 078861598 **UEI:** C8H9CNG1VBD9 **EIN:** 1136171197A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: JESSICA RUTH MOISE One Gustave L. Levy Place Box 1075 1 GUSTAVE L. LEVY PL, BOX 1075 NEW YORK, NY 10029 **Phone number:** (212) 824-8300 **Email:** jessica.moise@mssm.edu	**Signing Official:** JESSICA RUTH MOISE One Gustave L. Levy Place Box 1075 1 GUSTAVE L. LEVY PL, BOX 1075 NEW YORK, NY 10029 **Phone number:** (212) 824-8300 **Email:** jessica.moise@mssm.edu
Human Subjects: NA	**Vertebrate Animals:** NA
hESC: No	**Inventions/Patents:** No

B. OVERALL ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

AIM 1: To convert the existing data collected in the Selikoff Centers of Occupational Health since 2002 into a usable database for comparative analysis of health conditions affecting the World Trade Center General Responder Cohort (WTC-GRC).

AIM 2: To build a new occupational cohort serving as a comparison to the WTC-GRC in the longitudinal assessment of health and aging trajectories. Enrollment will consider matching of age, sex, race, ethnicity, and occupation with the WTC General Responders Cohort . Recruitment will be conducted using the database developed through Aim 1 and through outreach efforts.

AIM 3: To utilize the comparison cohort to determine if gastroesophageal reflux disease (GERD) incidence in the WTC-GRC differs from an unexposed worker population. We recently investigated GERD
incidence among the WTC-GRC but did not have an appropriate external unexposed population. We can utilize the comparison cohort developed through this project to perform a reanalysis.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Not Applicable

Project Title: New York Area Workers Cohort: Comparator Cohort for the World Trade Center General Responders Cohort (5 U01OH011487-03-00)

Project period: 07/01/2018 - 07/31/2023

Abstract

World Trade Center (WTC) first responders have suffered numerous diseases and conditions as a result of their efforts on 9/11 and afterwards. Higher than expected rates of certain cancers have been reported, such as multiple myeloma, prostate, and thyroid. Also reported are relatively high rates of post-traumatic stress disorder, anxiety, depression, and sleep apnea. Although the WTC General Responders Cohort (WTC-GRC) consists of occupational groups, the comparator groups for all of these reports were either national or local and were composed of members of the general population, not occupational groups. The purpose of this project is the development of a unique occupational cohort without WTC exposures to be used for valid estimates of the health of the first responders.

The specific aims of the project include: 1) converting existing data into a usable database for comparative analyses of WTC-related health conditions; 2) building a new occupational cohort to serve as a comparison in the longitudinal assessment of health in the WTC-GRC; and 3) utilizing the newly created comparison cohort to determine if GERD incidence in the WTC-GRC differs from an unexposed worker population.

List of Terms and Abbreviations

World Trade Center General Responder Cohort (WTC-GRC); Selikoff Centers for Occupational Health (SCOH); Mount Sinai Data Warehouse (MSDW)

Section 1. Significant or Key Findings

Queries were created and fulfilled by institutional resources at the MSDW, allowing the creation of the database for the New York Workers Cohort *(Specific Aim #1)*. The database was then utilized to identify eligible persons in order to extend an invitation to join the cohort. If potential participants elected to join the study and completed consent, the database was also utilized to collect clinical data on cohort members.

The resulting occupational workers cohort was created from members of the working population of the tristate area (*Specific Aim #2)*. While the composition and distribution of occupations was not entirely reflective of the WTC-GRC, it was reflective of the shifting trends of workers. Namely, it was largely female and older. Both characteristics have been reported to currently comprise a larger proportion of the workforce, a trend that is expected to continue. Specific results are pending analysis, but promise to give further insight on workers, their health, and occupational exposures.

The result of the project are expected to improve the quality of occupational health related studies, and thus, treatment to address these health conditions. Where possible, the cohort would provide an occupational match comparator, which will also match exposure risk, to improve estimates of disease incidence and prevalence in order to more accurately reflect the true rate in the WTC-GRC. Results from

this study aim to further improve our knowledge and understanding about exposures to 9/11 toxins and stressors. Additionally, the cohort will also expand occupational related knowledge about the health of the current workforce and the impact of their exposures.

Section 2. Scientific Report

Introduction

On the 11th of September 2001, two planes deliberately crashed into the World Trade Center (WTC) towers in lower Manhattan. At collision, they demolished the buildings and within minutes killed 2,753 people. The destruction they caused also released a plume of toxins into the air. At the site, the Pile—remains of the buildings—smoldered for the next three months. Neither the release of the toxins nor the burning Pile deterred tens of thousands of first responders who rushed into harm's way. First to look for survivors and, after it became clear there were very few, to search for human remains. The toxic dust cloud created by the 1000 C fireball was composed of asbestos, pulverized glass, cement, lead, polycyclic hydrocarbons, dioxins, pesticides, heavy metals, and polychlorinated biphenyls [1].

After responding to the events on September 11th, 2001, numerous diseases and conditions have been reported in the first responders involved its rescue, recovery, and clean-up efforts. In particular, aero-digestive disorders have seen higher than expected rates, including sinusitis, asthma, interstitial lung disease, and gastroesophageal reflux (GERD) [2, 3]. Other conditions are also commonly reported, such as multiple myeloma, thyroid and prostate cancers, post-traumatic stress disorder (PTSD), anxiety, depression, and sleep apnea [4, 5]. In response, the World Trade Center General Responders Cohort (WTC-GRC) was created [6].

The WTC-GRC is currently being followed in New York City region clinics tracking approximately over 90,000 members who suffer from an excess of illnesses previously mentioned [7, 8]. Many published articles, medical and lay press, have addressed the health status of first responders with respect to the extent of disease and treatments available to treat these illnesses in this group. However, the rate of these and other apparent diseases are drawn utilizing comparisons from national datasets such as the National Health and Nutrition Examination Survey (NHANES) and the Surveillance, Epidemiology, and End Results (SEER) programs. Occasionally, New York City or state cancer registries are used as well as those from nearby states [5]. Ideally for occupational epidemiology studies to be valid, a comparison cohort should be one that is exactly the same as the exposed group but without the exposure [9]. Using the aforementioned comparisons of the general population could potentially be introducing confounders or other biases [10].

First, the general population includes individuals who are diseased, institutionalized, and generally older than WTC responders. As a result, exposures and age-related disease risk may not be comparable to the first responder population. Second, the rates of diseases in this population may naturally be lower than the general population because of the Healthy Worker Effect (HWE) [10, 11]. The Healthy Worker Effect entails workers exhibiting lower overall death and disease rates in comparison to the general population. It occurs because relatively healthy individuals—compared to older or sicker individuals—are more likely to be employed and fit for continued employment [10]. Not controlling for this effect in comparisons could lead to an underestimation of the exposure effect.

It is also important to acknowledge that the WTC-GRC is an aging cohort introducing health problems associated with aging. As the cohort ages, it will become crucial to have an appropriate comparison group. An aging cohort will also allow study of understudied occupation groups, namely older general workers and female workers [12, 13]. No such cohort exists but is imperative in understanding the health impacts on the aging and female workers from the WTC-GRC.

The purpose of this project is to establish an effective comparison group to be used specifically for analyzing disease data from the WTC-GRC. The comparison cohort is expected to be matched on several variables, including age, sex, race, ethnicity, and occupation, in order to estimate more accurate disease rates reflected on their actual exposure to the dust cloud and other toxins in the area.

The study aims to do the following: 1) convert existing Selikoff Centers for Occupational Health (SCOH) data into a usable database for comparative analyses of WTC-related health conditions, 2) build a new occupational cohort to serve as a comparison in the longitudinal assessment of health in the WTC-GRC, and 3) utilize the newly created comparison cohort to determine if gastroesophageal reflux disease (GERD) incidence in the WTC-GRC differs from an unexposed worker population.

Methods

Creating the Database (Study Aim #1)

The database for the NY Workers Cohort was created from queries submitted and fulfilled by the Scientific Computing Group at Mount Sinai. The WTC-GRC data dictionary, from the EPIC electronic health records, was adapted for the cohort database. Once created, the database was used to identify study eligible participants; and, if consented, allow collection of clinical data for cohort members.

Recruitment for the NY Workers Cohort (Study Aim #2)

The NY Workers Cohort was recruited predominantly utilizing the database. At the inception of the project, recruitment plans included two primary modes of recruitment, with the first being invitations for staff to participate in in-person events hosted by the Selikoff Centers for Occupational Health (SCOH) and the second utilizing the cohort database. However, design and logistical challenges prevented the onset of recruitment from occurring before the COVID-19 pandemic arrived. As a result, once staff was prepared to welcome participants into the cohort in early in-person events were cancelled indefinitely. Therefore, contact with potential participants was originally via e-mail if they met inclusion criteria: adults (defined 18 years or older), employed or retired workers including those experiencing temporary job loss, and be ineligible for participation in the WTC-GRC. Unfortunately, despite the best efforts from staff to recruit remotely through e-mail, recruitment rates were projected to be too low.

After it became clear in-person recruitment activities in SCOH would remain remote due to the continuing effects of the COVID-19 pandemic, staff decided to expand the online presence of the *NY Workers Cohort*. A social media recruitment campaign was drafted by staff. This included creating new visual elements, investing in a marketing campaign, and create a new, more engaging website. The individual leading these efforts left in the middle of creating all of these elements which forced study staff to scale down the campaign. Ads for social media were purchased to help bolster the social media

campaign, raise awareness, and recruit participants in the target population. Even after these attempts, recruitment rates remained low.

Upon meeting with the advisory panel for the study, staff began to create an alternative method to recruit members via texts, but still using the cohort database. After receiving approval for the new strategy, and adapting current recruitment materials for text-based interface, staff began to welcome new participants using text messages. While the recruitment rate remained low, it climbed significantly during this phase. By the time this new strategy was implemented, staff were informed that the online consent platform being used to recruit was being decommissioned.

Staff was able to pivot from this consent platform to using a e-consent framework embedded in REDCap—the platform where survey questionnaires were being hosted, collecting, and storing study data. Due to the surge in data being stored in REDCap, memory capacity was exceeded and multiple iterations of this project were needed in order to continue recruitment.

New regulations were introduced regarding text messages by the organization being utilized to text participants. It was communicated to staff that under these new regulations, text messages to invite participants to the study could not continue and all text-based recruitment ceased. Staff returned to relying solely on e-mail invitations to eligible participants using the cohort database. Through the entirety of the recruitment phase for the cohort, staff continued to be invited to union boards and online presentations through SCOH but recruitment rates did not improve significantly. At the end of recruitment, all eligible participants in the database were reached via e-mail or text message to join the study.

Results and Discussion

The NY Workers Database (Study Aim #1)

From the queries, a total 491,139 participants were identified as eligible and contacted. Of those contacted, 1,920 responded to the invitation to join the *NY Workers Cohort* (Table 2; Figure 1). From the total responses received, 180 participants declined participation and 840 consented to join the study (Table 2; Figure 1). The remaining responses were incomplete.

The NY Workers Cohort (Study Aim #2)

Members enrolled in this cohort were primarily female (69%; Table 1). The mean age of this cohort also skewed older (50 years ± 14; table 1). The majority of the participants reported their race as white in comparison to other race categories (Table 1). This cohort was highly educated with the majority of participants reporting having a bachelor's degree or higher of education (table 1). Despite high education levels, less than half of the participants reported income levels above $100,000. In fact, distribution of household income was distributed evenly across many of the income brackets (Table 1). Approximately 3 out of 4 participants reported currently working. Of those who reported being unemployed, the majority were retired. Very few participants reported being students (Table 1). Furthermore, the majority of participants reported not being a part of any union group (76%; Table 1).

To our knowledge, we are the first US occupational cohort to be predominantly female with workers from a variety of occupational backgrounds, ranging from the hospitality sector to first responders [data not shown]. Female workers are often an understudied population in occupational studies despite being

a large proportion of the total workforce [13, 14]. This cohort may be able to help bridge this gap. Similarly, the older working population is also often underrepresented in occupational studies [15]. Seeing as the cohort skews older, findings derived from the data collected thus far will add to the conversation of how occupational exposures impact worker's lives in all age groups, including older individuals.

Public Health Impact and Conclusion

While we recognize the cohort created may not mimic the composition of the WTC-GRC exactly, future analysis are expected to contribute significantly to occupational studies in areas that are understudied. Due to the hardships encountered during the last months of recruitment, our analysis and publication timeline was pushed farther back than originally anticipated. In the next few months, study investigators are expected to continue cleaning and carrying out analysis of the data in order to prepare manuscripts for publication.

Descriptive Characteristic	N = 840
Age (in years)	
Min	20
Max	88
Mean (SD)	50 ± 14
Sex: n (%)	
Female	547 (69%)
Male	243 (31%)
Education: n (%)	
No high school	0 (0)
Some high school	5 (1%)
High school graduate	32 (4%)
Technical school	7 (1%)
GED or equivalent	7 (1%)
Some college, no degree	88 (11%)
Associate's Degree (occupational, technical, or vocational)	24 (3%)
Associate's Degree (academic)	23 (3%)
Bachelor's Degree	248 (31%)
Master's Degree	241 (30%)
Professional School Degree	74 (9%)
Doctoral Degree	45 (6%)
Race: n %	
American Indian or Alaska Native	15 (2%)

Asian	52 (6%)
Black or African-American	141 (17%)
Native Hawaiian or Pacific Islander	3 (0%)
White	539 (64%)
Income: n %	
$0-$10,000	29 (4%)
$10,001-$20,000	38 (5%)
$20,001-$30,000	44 (6%)
$30,001-$40,000	47 (6%)
$40,001-$50,000	51 (6%)
$50,001-$60,000	45 (6%)
$60,001-$70,000	53 (7%)
$70,001-$80,000	48 (6%)
$80,001-$90,000	46 (6%)
$90,001-$100,000	53 (7%)
$100,001-$110,000	55 (7%)
$110,001-$120,000	23 (3%)
$120,001-$130,000	34 (4%)
$130,001-$140,000	21 (3%)
$140,001-or above	171 (21%)
Current Employment Status: n %	
Currently Working	445 (75%)
Disabled or on medical leave	37 (24%)
Laid off or unemployed	35 (23%)
Retired	56 (37%)
Student	5 (3%)
Members of a Work Union: n %	
Yes	141 (24%)
No	453 (76%)

Table 1. Cohort summary characteristics. The above characteristics are described for the entirety of the cohort (N = 840); data was not reported for the following categories: 'Other', 'Don't Know', and 'Refused."

Enrollment	**Totals (N)**
Cumulative contacts	491, 139
Responses received	1,920
Consented to participate	840
Declined to participate	180
Ineligible responses	189
Incomplete responses (neither consented nor declined)	711

Table 2. Cumulative enrollment. A summary of the cumulative recruitment responses and outcomes are described.

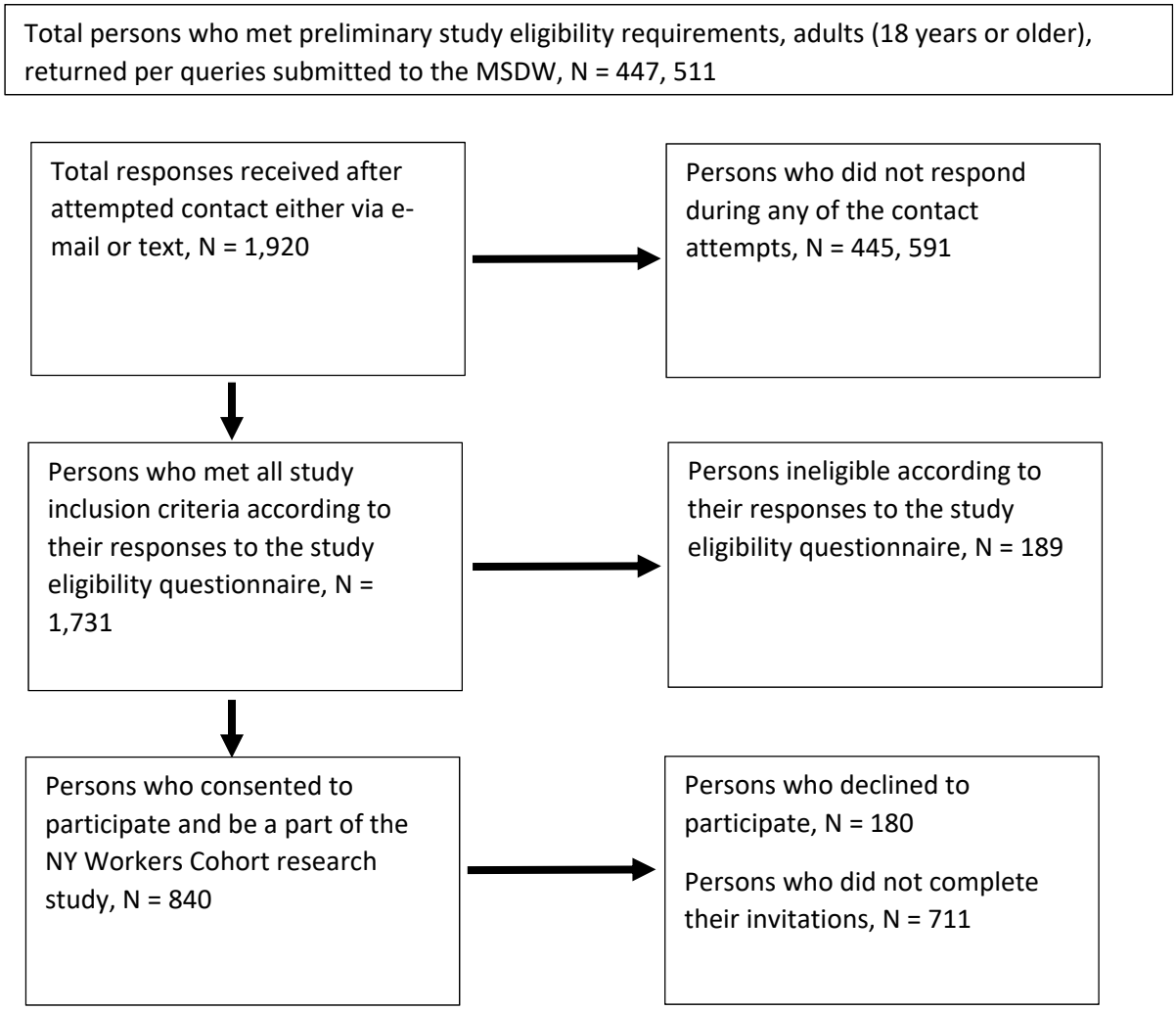

Figure 1. Diagram showing recruitment responses of persons contacted during enrollment period of the NY Workers Cohort.

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C. OVERALL PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Category	Explanation
Other	https://icahn.mssm.edu/workersstudy [Internal website (within Mount Sinai) intended to disseminate information regarding published results from the project]

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. OVERALL PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
SLTEITELBAUM	Y	TEITELBAUM, SUSAN L	BS,MPH,PHD	PD/PI	1.2	0.0	0.0			NA
HARARI	N	Harari, Homero	SCD	Co-Investigator	1.2	0.0	0.0			NA
NABEEI01	N	Nabeel, Ismail	MBBS, MPH	Co-Investigator	1.8	0.0	0.0			NA
	N	Li, Qian		Data Analyst	7.2	0.0	0.0			NA
	N	Valle, Carolina	MPH	Non-Student Research Assistant	12.0	0.0	0.0			NA
	N	Dent, Laura		Writer	2.4	0.0	0.0			NA

Glossary of acronyms:
S/K - Senior/Key
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RS - Reentry Supplement
DS - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Not Applicable

D.2.b New Senior/Key Personnel

Not Applicable

D.2.c Changes in Other Support

Not Applicable

D.2.d New Other Significant Contributors

Not Applicable

D.2.e Multi-PI (MPI) Leadership Plan

Not Applicable

E. OVERALL IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

NOTHING TO REPORT

G. OVERALL SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?

Not Applicable

G.4.b Inclusion Enrollment Data

File(s) uploaded:
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G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT No foreign component
G.10 ESTIMATED UNOBLIGATED BALANCE Not Applicable
G.11 PROGRAM INCOME Not Applicable
G.12 F&A COSTS Not Applicable

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title: Development and implementation of a comparison occupational cohort for the WTC GRC

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	1	1	0	0	0	0	0	0	0	**2**
Asian	25	16	1	2	1	0	1	0	0	**46**
Native Hawaiian or Other Pacific Islander	0	0	0	1	0	0	0	0	0	**1**
Black or African American	79	18	0	17	3	0	2	0	0	**119**
White	301	156	3	36	12	1	2	3	0	**514**
More Than One Race	17	7	0	9	1	1	2	0	0	**37**
Unknown or Not Reported	11	7	0	33	14	0	9	3	44	**121**
Total	**434**	**205**	**4**	**98**	**31**	**2**	**16**	**6**	**44**	**840**

I. OVERALL OUTCOMES

I.1 What were the outcomes of the award?

Queries were created and fulfilled by institutional resources at the MSDW, allowing the creation of the database for the New York Workers Cohort. The database was then utilized to identify eligible persons in order to extend an invitation to join the cohort. If potential participants elected to join the study and completed consent, the database was also utilized to collect clinical data on cohort members.

The resulting occupational workers cohort was created from members of the working population of the tristate area. While the composition and distribution of occupations was not entirely reflective of the World Trade Center – General Responders Cohort, it was reflective of the shifting trends of workers. Namely, it was largely female and older. Both characteristics have been reported to currently comprise a larger proportion of the workforce, a trend that is expected to continue. Specific results are pending analysis, but promise to give further insight on workers, their health, and occupational exposures.