

# Supporting Statement For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)  
Biomonitoring of Great Lakes Populations Program II

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PART B. Collections of Information Employing Statistical Methods

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ATSDR Division of Toxicology and Human Health Sciences  
Angela Ragin-Wilson, PhD  
Program Official  
Phone: 770-488-3807  
Fax Number: 770-488-7187  
Email: ARagin@cdc.gov

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## B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

### OVERVIEW

NYSDOH will look at two subpopulations of adults living in Syracuse, NY who are known to eat fish from Onondaga Lake. Onondaga Lake is a 4.5 square mile highly polluted Great Lakes Basin water body located in the City Syracuse, the Towns of Salina, Geddes, and Camillus. The lake drains approximately 285 square miles of the surrounding areas. Because of extensive pollution, the lake was proposed to the National Priority List on May 10, 1993, and officially listed on December 16, 1994. The Onondaga Lake superfund site consists of the lake itself, seven major and minor tributaries, and upland sources of contamination to the site, of which there are eleven. The lake flows into the Seneca River, then into the Oswego River and ultimately Lake Ontario. As a result of past industry, Onondaga Lake waters are contaminated with mercury, and sediments are contaminated with PCBs, pesticides, creosotes, heavy metals (including lead, cobalt and mercury), PAHs and volatile organic compounds such as chlorobenzene. Fish caught from Onondaga Lake have the highest mercury levels in NYS. Detailed information about the Onondaga Lake site history and current progress of remedial actions can be found at the EPA website, <http://www.epa.gov/region02/superfund/npl/onondagalake>.

The NYSDOH biomonitoring program is not research and the biomonitoring results will not be generalized beyond the City of Syracuse, NY and the defined subpopulations under study. An overview/diagram of the information collection process for the state program can be found in Attachment 3.

### B.1. Respondents and Sampling Methods

#### Respondent Populations

The NYSDOH has two respondent populations: (1) the Burmese and Bhutanese refugee community in Syracuse whose culture is known to eat a substantial amount of fish from Onondaga Lake; (2) an urban subsistence population who rely on fish from Onondaga Lake as a source of food. The desired number of respondents to complete the study was primarily determined by the level of available program funding (n=300 for refugees and n=100 subsistence anglers).

Table 1. *Number of respondents by target subpopulation in Syracuse, NY*

	Respondents	Completion Rate
<b>Refugees from Burma and Bhutan</b>		
<i>Referred=606</i>		
Eligibility Screening	424	70% (424 of 606)
<i>Number Eligible=335</i>		

Complete Study	300	90% (300 of 335)
<b>Urban Subsistence Anglers</b>		
<i>Referred=300</i>		
Eligibility Screening	180	60% (180 of 300)
<i>Number Eligible=125</i>		
Complete Study	100	80% (100 of 125)

### **Refugees from Burma and Bhutan:**

The largest numbers of refugees in the Syracuse area are from Burma, followed by Bhutan and Somalia. Refugees from Burma (Myanmar) began arriving in large numbers in 2007; since 2001, a total of 1,857 Burmese refugees have resettled in Syracuse. In 2008, Bhutanese refugees began arriving, and they continue to be resettled in Syracuse. The total number of Bhutanese resettled in Syracuse since 2008 is 1,427. (The World at Our Doorstep, 2012-2013, Report No. 329) Actual numbers of recently settled refugees are expected to be higher than the official estimates because once refugees arrive in a state, they are free to relocate elsewhere, and secondary migration to join an already established refugee community is common.

The resettlement process for refugees in Syracuse is coordinated by three agencies that work collaboratively to provide services: Catholic Charities of Onondaga County, InterFaith Works and the Syracuse City School District Refugee Assistance Program. The City of Syracuse welcomes about 800-850 refugees per year; the majority of which are Burmese (Karen, Chin, Karenni) and Bhutanese (ethnically Nepali). (Source: Refugees In Syracuse; The Resettlement Process, a presentation by Catholic Charities of Onondaga County, InterFaith Works and the Syracuse City School District Refugee Assistance Program, Oct. 2013).

### **Urban Subsistence Anglers**

The target subsistence fishing population is presumed to reside primarily in the low-income Southwest area of Syracuse, especially in those tracts with poverty rate near or higher than 40% (Attachment 6). This map shows the demographics of the census tracts with a poverty rate near or higher than 40% in this neighborhood. Populations in most of these tracts are more than 50% minority; the poverty rates range from 37.5% to 73.9%. The estimated total population living in these tracts is 32,720, with 53.8% African Americans, 1.3% Native Americans, 1.2% Asians, 15.3% Hispanics, and a total of 73.4% minorities. Among this population, 56% are aged 20-64 years old, and 48.5% are males.

The low-income population of Syracuse primarily resides in an area just south of the Syracuse business district known as the Southwest neighborhood. Among the 19 Census tracts in Syracuse with a 40% or higher poverty rate (Attachment 6), twelve are in this area, followed by four tracts in the Eastside area (34, 35, 43.01, and 45) and three tracts (5.01, 16, and 24) in the Northside area of Syracuse. The Southwest and Eastside neighborhoods are defined and divided by Interstate 81, a north-south route which is locally thought of as Syracuse's "Berlin Wall" that divides the city into distinct neighborhoods (Seward Z, 2012). The minority populations in the lowest-income census tracts in this Southwest area are predominantly African-American and

Hispanic; the Eastside areas bordering route 81 comprise culturally diverse university and residential neighborhoods (TNT Neighborhood Planning Council, 2011).

### **Sampling method**

Respondent-driven sampling (RDS) will be used to sample both target populations. RDS is suitable for reaching “hidden” populations for which there is no known sampling frame (Lee 2011; Lansky 2007). RDS has been shown to increase efficiency and decrease cost compared to other sampling designs and has been shown to be suitable for refugee populations (Sabin 2011). RDS uses a chain referral methodology to recruit from a target population whose members are interlinked by a strong social network. As part of grant development and feasibility assessment, NYSDOH spoke with refugee support agencies and neighborhood revitalization agencies of Syracuse’s inner city. Information gathered indicates that RDS will be an effective approach for recruiting these target populations. Both target populations are socially connected culturally, geographically, and, to some extent, politically. It is also reasonable to assume that individuals will have knowledge of each other’s fishing and fish consumption habits.

RDS begins with the selection of seeds from the target population to initiate a chain referral process. Seeds must have special attributes that will ensure effective recruitment. Seeds should have large social network sizes, be respected by members of the target population, be able to convince others to participate in the study and have some interest in the study goals (Heckathorn, 1997; 2002). Seeds that comprise important characteristics will ensure that the sample reaches into all sub-networks of the target population.

Formative assessment will be used to assist in the selection of effective seeds. The formative assessment will focus on learning cultural, social, economic, geographic, and other factors that affect community cohesion and social networks in the target populations. For each target population, NYSDOH staff will meet with 3-4 people consisting of leaders and service providers of local organizations to help understand attributes of community members and sub-networks. The program will use information learned during the formative research phase to identify the number of seeds and seed characteristics to select. For example, if women and men have limited social interactions (are less likely to recruit peers of the opposite sex), the program will select both male and female seeds; or if social interactions are closer among certain ethnic or political subgroups, the program will identify seeds based on these characteristics. Following the formative assessment, local community organization leaders will assist in identifying the seeds.

Seeds are treated as any other participant (i.e., screened, interviewed, etc.) and must meet the eligibility requirements set up at the outset of the study. After the seeds complete the clinic data collection activities, they become recruiters and are trained to recruit their peers from their social network. Each recruit who completes the clinic data collection will likewise be invited to be a recruiter. Each recruiter is given three referral coupons and three payment coupons (Attachment 4). The coupons have the name, address, and a photograph of the project site, the dates during which the coupons are valid, and the same unique coupon number. The coupon number allows us to link the recruiter to his/her recruits. In addition, the referral coupon does not list any information about the project so that the recruiter must actively recruit new participants.

To successfully use RDS, we plan to provide incentives for participation and successfully referring eligible participants, ration the coupons (one - three per recruiter), track the coupons associated with each recruiter (including the seeds), record the network size of each recruiter, and document the relationship of the recruit to the recruiter (Semaan, 2010; Aldana and Quintero, 2008). In addition, to avoid a clustering effect, seeds and recruiters will be specifically told to refer people who are not part of their household. As we reach our target enrollment, we will adjust the expiration date on the coupons and reduce the number of coupons per participant (for example, two coupons when we reach 80% of the enrollment goal, one coupon when we reach 95%). The prior 2010 study identified 5 seeds and started with 3 seeds. The 3 referral chains and recruitment moved fast with the program holding one screening clinic per week. With the initial 3 seeds, the program reached the target goal of 200 participants in 11 weeks. The proposed study likewise will identify additional seeds at the study onset to use if needed.

Each set of recruits from a single recruiter is a recruitment “wave.” The recruitment process continues until either enrollment goals have been met or equilibrium is reached. Equilibrium is the composition of the sample that would be expected if the initial participants had been selected at random. As part of RDS we will track the characteristics of the participants, including sex, age, and the neighborhood where they reside.

We expect that we can reach our recruitment goals quickly using RDS, provided that each participant can make three referrals and that participation is high. For example, if one seed (wave 0) recruits three people, all three show up at the project site, and two are eligible and participate, this wave (wave 1) produces two new participants. If this scenario continues through four waves, one seed will generate 31 participants, six seeds generate 186 participants, and 10 seeds generate 310 participants. Some seeds may “dry out”; therefore, if possible, it is preferable to balance the number of seeds against the number of recruitment waves expected to reach the enrollment goal.

### *Completion rate*

#### Burma and Bhutan

Using a networking driven sampling strategy appropriate for ‘hidden populations’ such as refugees from Burma and Bhutan living in Syracuse, NY who consume fish caught from Onondaga Lake, a 90 % study completion rate of eligible referrals who come to the clinics is projected. A high participation rate can be achieved because the RDS strategy uses peer-recruitment. The initial recruits, referred to as seeds, will be individuals who are well-connected and respected in the community and interested in participating in the project. The respondent driven sampling strategy affords a dual incentive system that helps maximize response. In addition to the typical material incentive that programs provide as a token of appreciation, RDS uses peer-recruitment and thus has a social incentive for people to participate. The enrollment goal for the Burmese and Bhutanese target population is 300 persons who eat fish caught in Onondaga Lake. In the prior 2010 study, 311 referrals were made, 228 (74% of 311) referrals came to clinics for eligibility screening, 203 (89% of 228) were eligible and all 203 (100% of 203) eligible people proceeded through the study data collection. Recruitment stopped when the

program reached the target goal of 200 participants. A report on the RDS method evaluation based on the 2010 study is not available at this time.

NYSDOH will collaborate with local organizations such as Catholic Charities of Onondaga County (<http://www.ccoc.us/>) and Interfaith Works of Central New York Refugee resettlement Program to support outreach and study recruitment, and to maximize response rates. These agencies provide many services to the refugees including employment, health, interpretation, family support groups, transportation, and educational and legal consult. Catholic Charities refugee resettlement services include assistance with applying for jobs, registering for English language classes, locating translators and housing, and securing medical care. Catholic Charities and Interfaith Works also partner with Onondaga County, the city of Syracuse, the Syracuse City School District and numerous other agencies to ensure a cooperative, collaborative approach to resettlement activities.

### Urban Subsistence Anglers

The projected number of referrals and subsequent completion rates using a RDS sampling strategy to recruit urban subsistence anglers living in Syracuse, NY who consume fish caught from Onondaga Lake are presented in Table 1. At each stage of RDS sampling, a lower completion rate is projected for subsistence anglers than the Burmese and Bhutanese population because people within this network are not as closely linked socially as people in the refugee community. Subsistence anglers who receive coupons and who are eligible may be less likely to participate because they are more loosely tied to the person who gave them the coupon. They may feel less responsible to the person who referred them, and as a result, may be less likely to follow through by participating. Still a high participation rate can be achieved because the RDS strategy. NYSDOH will collaborate with local organizations such as Jubilee Homes of Syracuse, Inc. (<http://www.jubilee-homes.com/>) and Syracuse Model Neighborhood Facility, Inc. (<http://smnfwcc.org/>) to support outreach and study recruitment, and to maximize response rates. Jubilee Homes is a nonprofit organization with a wide and varied approach to the revitalization of the Southwest side of the City of Syracuse. Jubilee Homes of Syracuse operates programs to address the needs within this geographic footprint. Syracuse Model Neighborhood Facility, Inc., a non-profit organization established in 1974, is the managing entity of the City of Syracuse owned Southwest Community Center. The Southwest Community Center provides services and activities designed to identify and reinforce the strengths of individuals, families and communities.

## **B.2. Procedures for the Collection of Information**

For recruitment, enrollment and screening of non-English speakers, the local organizations assisting with the program will help identify and train interpreters to serve as interviewers. The recruitment script, eligibility survey, consent form and questionnaire interview will be translated into Burmese, Bhutanese and Spanish and administered by trained interpreters for corresponding non-English speakers. All contact, consent and data collection documents can be found in Attachment 8.

Eligibility will be determined using a screening survey (Attachment 8a and 8e). By definition, seeds are eligible to participate. In addition to the eligibility criteria listed above, to be eligible, recruited individuals must know the recruiter, not be a family member, and not have already participated in the project (as subsistence angler or Burmese and Bhutanese who eats their catch). After confirming the prospective participant's eligibility, he/she will be given a quiet place to read the consent document, which will be available in English and the primary Burmese, Bhutanese or Spanish language. If a participant expresses difficulty with reading, the consent document will be read to them by an interviewer or trained interpreter. Before beginning any procedures, a trained interviewer will ask the participant if he/she has any questions. When the participant's questions have been answered to his/her satisfaction, the participant and the interviewer will sign the consent form (Attachment 8b and 8f). After obtaining signed informed consent, participants will be administered a questionnaire interview (Attachment 8c and 8g), complete a network size questionnaire for RDS (Attachment 8d and 8h), and asked to provide a blood and urine sample.

Upon completing the project activities, each participant will be invited to be a recruiter. If the participant is interested, he/she is trained to recruit other persons like him/herself. Each recruiter is then given three referral coupons and three payment coupons (Attachment 4). The coupons have the name, address, and a photograph of the project site, the dates during which the coupons are valid, and the same unique coupon number. The coupon number allows the program to link the recruiter to his/her recruits. In addition, the referral coupon does not list any information about the project so that the recruiter must actively recruit new participants. The recruitment steps are as follows:

1. The recruiter gives the referral coupons to up to three people in his/her network (i.e., recruits) and keeps the payment coupons.
2. The recruit takes the referral coupon to the project site, where he/she will be screened for eligibility, will be invited to participate (if eligible), and will complete the procedures.
3. The recruiter returns the payment coupons to the project site and will receive a gift card if the corresponding recruits were eligible and participated in the project.

At the end of the appointment, the participant will be given a copy of the consent document and gift cards for \$75 as a token of appreciation for participating in the project. If the participant chooses to be trained to recruit new participants, he/she will be given a \$15 gift card for each referral who is screened, eligible, and agrees to participate. In addition to the clinic incentives, participants will be given at most \$45 for recruiting three peers. Referred individuals who complete the screening interview but are ineligible or refuse to participate will be given a small gift for their effort (e.g., a T-shirt and fishing license case with the fish advisory website link). No gift cards for any incidental expenses (such as travel) will be provided.

### *Planned analyses*



Descriptive statistics will be used to describe the exposure distribution in each target population. For each target population, the analysis and presentation of results will include geometric mean and percentile calculations, calculated consistent with the assumptions for the RDS method. Specifically, social network size data (Attachment 8d and 8h) will be used to weight estimates. Recruiter-recruit connections data (Attachment 8d and 8h) will be used to generate relative inclusion probabilities (Heckathorn, 1997; 2002). This approach will allow us to characterize the distribution of local exposure. Health based exposure concentrations are not available for most of the chemicals of interest (with the exception of lead), so it will not be possible to characterize the percent of the population that has levels of concern. Rather, we would be able to descriptively report how the distribution of each target population compares with the nationally representative population estimates associated with the National Health and Nutrition Examination Survey (NHANES) *Fourth National Report on Human Exposure to Environmental Chemicals* or the corresponding *Updated Tables, February 2015* (See <http://www.cdc.gov/exposurereport/>). For instance, we might conclude that the target population tends to have exposures that are more similar to what is seen in the 95<sup>th</sup> percentiles of the national distribution. However, we will not be able to draw conclusions about the statistical significance of differences in geometric means or percentiles between the nationally representative population and our RDS sample because the underlying assumptions in the two samples are very different.

Respondents' individual exposure values will be reported back to them alongside reference values (Attachment 10). Specifically, for chemicals with a known health-based benchmark level, we will compare individual exposures to the benchmark level [e.g., a blood lead level greater than or equal to 10 micrograms per deciliter ( $\geq 10 \mu\text{g/dL}$ )]. For chemicals without health-based benchmark levels, individuals will be provided reference values associated with the distribution of concentration levels in the National Health and Nutrition Examination Survey (NHANES) *Fourth National Report on Human Exposure to Environmental Chemicals* or the corresponding *Updated Tables, February 2015* (See <http://www.cdc.gov/exposurereport/>) for comparison.

### **B.3. Methods to Maximize Response Rates and Deal with No Response**

As a means to promote trust with the state program and maximize response rates, the NYSDOH will work with community partners to conduct outreach, recruitment and enrollment, and screening activities. NYSDOH will collaborate with local organizations such as Catholic Charities of Onondaga County (<http://www.ccoc.us/>) and Interfaith Works of Central New York Refugee resettlement Program to support outreach and study recruitment, and to maximize response rates for the Burmese and Bhutanese refugee population. To assist in the recruitment of subsistence anglers, NYSDOH has partnered with Jubilee Homes of Syracuse, Inc. (<http://www.jubilee-homes.com/>) and Syracuse Model Neighborhood Facility, Inc. (<http://smnfswcc.org/>) to support outreach and study recruitment, and to maximize response rates.

A high participation rate can be achieved because the RDS strategy uses peer-recruitment. RDS has been shown to be an effective approach for recruiting target populations within social networks. The initial recruits, referred to as seeds, will be individuals who are well-connected and respected in the community and interested in participating in the project. The respondent

driven sampling strategy affords a dual incentive system that helps maximize response. In addition to the typical material incentive that programs provide as a token of appreciation, RDS uses peer-recruitment and thus has a social incentive for people to participate.

Participants will be given a \$75 gift card as a token of appreciation for participating in the project. As part of the RDS, if the participant chooses to be trained to recruit new participants, he/she will be given a \$15 gift card for each referral who is screened, eligible, and agrees to participate. In addition to the clinic incentives, participants will be given at most \$45 for recruiting three peers.

#### **B.4. Tests of Procedures or Methods to be Undertaken**

NYSDOH piloted the questionnaire interview and screening surveys among less than nine people representative of their target audience. Pilot testing served to identify questionnaire items that were not clear and to evaluate the burden that each item as well as total items posed. Questionnaire items were refined and items that posed a significant time burden for the information gained were eliminated.

#### **B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

##### **B.5.1 Study design and sampling plan:**

The study design and sampling plan were adapted from NYSDOH's prior experience with the FY 2010 biomonitoring of refugees and immigrants from Burma living in Buffalo (OMB Control No: 0923-0044). Modifications were developed as a collaborative process between ATSDR and state program staff.

**ATSDR:**

Wendy Wattigney, M.Stat.

Mathematical Statistician

770-488-3802

[WWattigney@cdc.gov](mailto:WWattigney@cdc.gov)

Zheng (Jane) Li, Ph.D., MPH

Acting Lead Environmental Health Scientist

770-488-7940

[ZhengJLi@cdc.gov](mailto:ZhengJLi@cdc.gov)

**New York:**

Syni-An Hwang, Ph.D.

Principal Investigator

Director, Bureau of Environmental & Occupational Research

New York State Department of Health  
518-402-7950  
[sah02@health.state.ny.us](mailto:sah02@health.state.ny.us)

Elizabeth Lewis-Michl, Ph.D.  
Chief, Community Exposure Research  
Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[ell01@health.state.ny.us](mailto:ell01@health.state.ny.us)

Julie Reuther, M.P.H.  
Project Coordinator  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Jar11@health.state.ny.us](mailto:Jar11@health.state.ny.us)

Edward Fitzgerald, Ph.D.  
Chair, Department of Epidemiology and Biostatistics  
School of Public Health  
University at Albany, SUNY  
518-402-1062  
[efitzgerald@uamail.albany.edu](mailto:efitzgerald@uamail.albany.edu)

Ralph R. Van Houten  
Assistant Regional Director  
NYSDOH  
335 Main Street East  
Rochester, NY 14604  
585-423-8072  
[rrv01@health.state.ny.us](mailto:rrv01@health.state.ny.us)

### **B.5.2 Questionnaire design**

The questionnaire survey was primarily designed as part of the *2010 ATSDR Biomonitoring of Great Lakes Populations Program* (OMB Control No: 0923-0044, expiration date 10/31/2015) through a collaborative process between ATSDR Project Officers, state program staff and state-specific consultants. The questionnaire survey developed for NYSDOH's FY 2010 biomonitoring of licensed anglers in the Niagara River area and Burmese living Buffalo was modified with regard to relevance of the current catchment area and target populations. Weekly conference calls were held for a two month period to determine questionnaire survey modifications among ATSDR program staff, state program staff and state consultants.

**ATSDR:**

Wendy Wattigney, M.Stat.  
Project Officer  
Mathematical Statistician  
770-488-3802  
[WWattigney@cdc.gov](mailto:WWattigney@cdc.gov)

Zheng (Jane) Li, Ph.D., MPH  
Program Supervisor (Acting)  
Lead Environmental Health Scientist  
770-488-7940  
[ZhengJLi@cdc.gov](mailto:ZhengJLi@cdc.gov)

**New York:**

Syni-An Hwang, Ph.D.  
Principal Investigator  
Director, Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[sah02@health.ny.us](mailto:sah02@health.ny.us)

Elizabeth Lewis-Michl, Ph.D.  
Chief, Community Exposure Research  
Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[ell01@health.ny.us](mailto:ell01@health.ny.us)

Julie Reuther, MPH  
Research Scientist 2  
Bureau of Environmental and Occupational Epidemiology  
Center for Environmental Health  
New York State Department of Health  
518-402-7950  
[jar11@health.ny.us](mailto:jar11@health.ny.us)

Edward Fitzgerald, Ph.D.  
Chair, Department of Epidemiology and Biostatistics  
School of Public Health  
University at Albany, SUNY  
518-402-0372  
[EFitzgerald@uamail.albany.edu](mailto:EFitzgerald@uamail.albany.edu)

Karen Nolan, M.P.H.  
Research Scientist  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Kxf07@health.ny.us](mailto:Kxf07@health.ny.us)

James Bowers, M.P.H.

Communication Specialist  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Jab25@health.ny.us](mailto:Jab25@health.ny.us)

June Moore, M.P.H.  
Research Scientist  
Community Exposure Research  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Jxb23@health.ny.us](mailto:Jxb23@health.ny.us)

Kamal-Nain Siag, M.P.H.  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Kss08@health.ny.us](mailto:Kss08@health.ny.us)

### **B.5.3 Data collection**

Elizabeth Lewis-Michl, Ph.D.  
Chief, Community Exposure Research  
Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[ell01@health.ny.us](mailto:ell01@health.ny.us)

Julie Reuther, MPH  
Research Scientist 2  
Bureau of Environmental and Occupational Epidemiology  
Center for Environmental Health  
New York State Department of Health  
518-402-7950  
[jar11@health.ny.us](mailto:jar11@health.ny.us)

Karen Nolan, M.P.H.  
Research Scientist  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950

[Kxf07@health.ny.us](mailto:Kxf07@health.ny.us)

Samira Ramadan, M.P.H.  
Research Scientist  
Community Exposure Research  
Bureau of Environmental & Occupational Epidemiology  
New York State Department of Health  
518-402-7950  
[Samira.Ramadan@health.ny.us](mailto:Samira.Ramadan@health.ny.us)

#### **B.5.4 Data Management**

Ming Liu  
Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[Ming.liu@health.state.ny.us](mailto:Ming.liu@health.state.ny.us)

#### **B.5.5 Data Analysis**

Ming Liu  
Bureau of Environmental & Occupational Research  
New York State Department of Health  
518-402-7950  
[Ming.liu@health.state.ny.us](mailto:Ming.liu@health.state.ny.us)