Information Collection Request

Examining In-Vehicle Exposures to Air Pollutants and Corresponding Health Outcomes of Commuters

Supporting Statement

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Fuyuen Yip, PhD, MPH
Team Lead, Air Pollution Team
Air Pollution and Respiratory Health Branch
EHHE/NCEH/CDC
4770 Buford Highway NE
MS F-58
Atlanta GA 30341
Phone: 770.488.3719
Fax: 770.488.1540
fyip@cdc.gov

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A.1 Circumstances Making the Collection of Information Necessary

Background

Exposure to gas-phase and particle-phase pollutants in the ambient atmosphere is known to have a negative effect on human health. Furthermore, results of many epidemiological and laboratory studies suggest that combustion-generated pollutants associated with motor vehicle traffic are of particular concern. We are requesting a one year approval for a new study: "Examining In-Vehicle Exposures to Air Pollutants and Corresponding Health Outcomes of Commuters" to examine in more detail the exposure to potentially harmful pollutants by commuters on Atlanta highways. Data collection is expected to take one year.

This study will include in-vehicle monitoring of chemically- and size-resolved particulate matter (PM) concentrations. The impact of f actors such as engine performance, vehicle ventilation rate and traffic congestion on in-cabin pollutant levels will be examined. We will also study the relative contribution of the emissions from the subject's own vehicle as compared to surrounding vehicular traffic and ambient PM sources. In addition, we will monitor several health outcomes that have previously been identified as potentially important by PM-related epidemiology, including heart rate and heart rate variability (HRV), systemic markers of inflammation and oxidative stress, and markers of airway inflammation including exhaled nitric oxide. Data on potential confounding factors such as in-vehicle noise levels and elevated stress levels experienced by participants operating vehicles in situations of high traffic volume will also be collected . Finally, data analysis will include general descriptive statistics, fixed and mixed effects regression models to identify factors influencing in-cabin pollutant concentrations, and an examination of associations between pollutant exposure and health outcomes, including both *a priori* models to examine previously-reported associations and exploratory models to examine novel hypotheses.

Previous Studies

Many previous studies have observed associations between ambient fine particulate matter (*i.e.*, particles smaller than 2.5 μm, termed $PM_{2.5}$) and a variety of adverse health outcomes including cardiovascular and respiratory disease [1-5]. Numerous epidemiologic studies have also suggested that specific sub-populations may be at greater risk for $PM_{2.5}$-mediated health effects due to their proximity and/or enhanced exposures to traffic-related pollution[6-17]. Exposure to vehicle-associated PM has been demonstrated to have a negative effect on lung function, particularly in susceptible individuals such as children[6,18] or those with asthma [19-21].

A potentially troubling implication of these previous studies is the possibility that persons who commute by automobile on a daily basis may comprise a vulnerable sub-population. Several exposure assessment studies have indicated that durations as brief as 30 minutes inside vehicles can contribute substantially to total daily exposures to volatile organic compounds [24,27-31], carbon monoxide [24,32], and particulate matter [22-26].

A thorough characterization of in-vehicle pollutant exposure is especially compelling and is currently a large gap in the current research. The duration of the average commute in the United States has increased steadily in recent decades to a national average of 25.5 minutes in each

direction[33]. The U.S. Census Bureau reports that over 40 million Americans spend at least an hour each day commuting to and from their place of work with 3.4 million people commuting at least three hours per day[33]. The Atlanta region is no exception to the national trend, and five metropolitan Atlanta counties rank in the top 100 U.S. counties with the longest commute times [34]. Commute times in the suburban counties of Dekalb, Cobb, Clayton and Gwinnett are particularly long (28.4–30.7 minutes), though even centrally-located Fulton County has an average commute of 26.9 minutes. The Atlanta Regional Commission estimates that commuting to or from a workplace comprises 22% of all daily trips taken in the Atlanta region[35], suggesting that daily commuters in this region both contribute substantially to the air quality burden and comprise a large potentially at-risk sub-population. A more complete understanding of in-vehicle exposures for the commuter population, especially those with asthma, is therefore becoming increasingly necessary.

Summary

The primary objectives of this study is to investigate the exposure of automobile commuters in the Atlanta region to hazardous air pollutants and to assess changes in indicators of cardiopulmonary status such as heart rate, heart-rate variability and biomarkers of airway and systemic inflammation and oxidative stress. These measurements will provide much needed data and insight into important aspects of both PM exposure assessment and epidemiology, especially among susceptible individuals such as those with asthma.

The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

Contribution to CDC's research agenda

A critical component of the mission of the National Center for Environmental Health, Centers for Disease Control, is to identify public health impacts from exposures to environmental contaminants. This research agenda will advance our understanding of how exposure to air pollutants while commuting on public roadways in the Atlanta area influences cardiovascular and respiratory health.

Privacy Impact Assessment

Overview of the Data Collection System

A total of 40 participants (20 adults with physician-diagnosed asthma and 20 healthy adults) living in the Atlanta metro area will be recruited for participation in this study. Participants will be excluded if they meet specific criteria including: ever being diagnosed with severe asthma, ever suffering a myocardial infarction, smoking tobacco products, or ever being diagnosed with a pulmonary disease such as emphysema, chronic obstructive pulmonary disease, or any type of lung cancer.

Participants will use their private vehicles to conduct a scripted morning commute. Each commute will last approximately 120 minutes and each subject will perform two commutes to assess for potential seasonal variability. The scripted commutes will be scheduled during peak rush hour periods and include areas of heavy traffic congestion within the metropolitan Atlanta area.

At least one day prior to their scheduled commute, participants will complete a one-time baseline questionnaire to assess medical history and general exposures. Baseline health measurements for blood pressure, lung function, lung inflammatory markers (e.g., exhaled nitric oxide, exhaled breath condensate), heart rate and heart rate variability, and biomarkers of systemic inflammation will also be conducted by a trained field technician and phlebotomist. These biomarkers include pro-inflammatory response cytokine, interleukin 6 (IL-6) and C-reactive protein (CRP). Several blood markers associated with thrombotic or coagulation processes have also been associated with air pollution exposures and will measured, including von Willebrand factor and fibrinogen. One day before the commute, a short symptom diary recording any respiratory symptoms will be completed by the participant. At the same time, the participant will begin to monitor his/her heart rate and heart rate variability using a Holter heart rate monitor.

On the day of the scripted commute, a field technician and phlebotomist will arrive at the subject's residence approximately one hour prior to sampling to conduct pre-commute health measurements similar to the baseline measurements and conduct the symptom diary. At the same time, the participant's private automobile will be equipped with a combination of continuous and time-integrated air pollution sampling equipment designed to measure in-vehicle concentrations of: a) continuous and integrated $PM_{2.5}$ mass concentrations; b) continuous elemental carbon; c) continuous size-resolved particle count; d) continuous carbon monoxide; e) integrated particulate organic speciation (e.g., Polycyclic Aromatic Hydrocarbons [PAHs], hopanes, steranes); f) integrated particulate trace element content; and g) continuous noise levels. Sampling equipment will be secured in the backseat of the vehicle with inlets placed near the driver's breathing zone. In addition to the in-vehicle pollutant measurements, ambient measurements will be measured to examine the association between in-vehicle concentrations and roadside and ambient monitoring data. Equipment recording information about the automobile's engine, speed, acceleration, location, and traffic congestion patterns will also be installed in the participant's automobile. All parameters will be measured during the commuting periods exclusively. All proposed sampling methods for this study are either commercially-available or have been extensively characterized in previous air pollution monitoring studies. Installation will take approximately 1 hour.

The two-hour scripted commute predetermined by Emory University will then be conducted by the participant. All commutes will end at Emory University General Clinical Research Center (GCRC). Upon arriving at Emory University, field technicians and GCRC staff will measure post-commute air flows, remove the equipment from the participant's automobile, and administer post-commute health measurements. These post-health measurements consist of the symptom diary and health measurements that were conducted before the commute to assess any potential changes in respiratory and cardiovascular health effects before and after the two-hour commute. These tests will be repeated three times—every hour for three hours—to assess for any lag times in physiological response to pollutant exposures. The information learned from these health measurements and diary entries before and after the commute, as well as the in-vehicle measurements, will be important in better understanding the potential acute health impacts

associated with exposures to in-vehicle traffic pollutants and respiratory and cardiovascular health, and whether urban commuters—especially those with asthma—should be viewed as a susceptible sub-population given their enhanced exposures to $PM_{2.5}$ and gas-phased pollutants.

Data collection instruments consist of two paper questionnaires: 1) the baseline questionnaire, conducted at least one day prior to the commute, on the participant's medical history and exposures (Attachment 3) and 2) a symptom diary, conducted two times before and three times after the commute, to record health symptoms relevant to this study (e.g., wheeze, cough) (Attachment 4). Information will be collected from study participants using personal interviews. This process will be conducted twice for each participant. Attachment 5 summarizes the in-vehicle exposure data collected using specific instrumentation during the scripted commute.

Items of Information to be Collected

Categories of Information in Identifiable Form (IIF) collected are as follows: name, phone number, date of birth, sex, and residential address.

Additional questionnaire information collected includes a health history with questions about education, asthma, past and current respiratory symptoms, smoking history, respiratory illnesses (such as bronchitis, hay fever), past and current cardiovascular symptoms, history of cardiovascular disease (such as heart attack or chest pain) and history of hospitalization. Other information collected includes proximity of the subject's residence and workplace to major sources of air pollution (such as highways).

Identifying information is necessary to facilitate the personal contact with respondents required to conduct the survey. The identifying information will remain with investigators at Emory University and will not be forwarded to CDC; however because Emory is a contractor for CDC and would have the link between name and ID number, the Privacy Act applies. Hard copies of questionnaires used for data entry at CDC will be identified by ID number only.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

We do not plan to host a website for this data collection.

A.2 Purpose and Use of the Information

The purpose of this data collection is to study the human health effects of exposure to air pollution while commuting by car on highways in Atlanta. The results from this study will be useful to transportation, environmental, and public health agencies at the federal, state, and local municipality levels. Many previous studies have shown the negative health effects of pollutants from traffic sources, and this study will specifically examine health effects on commuters who are operating vehicles directly in the source region of these pollutants. Knowledge of these health effects will be useful for determining future vehicle emission standards and ambient air quality standards, for improving the design of traffic corridors and city planning, and for promoting public awareness of the risks associated with exposure to traffic pollution.

If we do not collect this information, we will not be able to accurately assess the health risks associated with exposure to traffic pollution while operating a vehicle on major highways and address a current gap in the literature regarding these exposures.

Privacy Impact Assessment Information

IIF such as name, phone number, date of birth, and residential address will be collected, along with the personal information regarding each individual's history of cardiovascular and respiratory illnesses.

IIF is necessary to facilitate the personal contact with respondents required to conduct the survey. IIF will remain at Emory University and will not be forwarded to CDC. IIF data sharing will be done in accordance with Emory University policies and procedures because only Emory University will maintain the link between name and study ID number; CDC will not maintain IIF. Hard copies of questionnaires used for data entry at CDC will be identified by study ID number only.

While smoking and information on level of stress are being collected, which are considered by at least a portion of the population to be sensitive, no highly sensitive information is being collected so there will be little effect on respondents' privacy.

A.3 Use of Improved Information Technology and Burden Reductions

This collection of information will not use automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The study instruments require collection of only the minimum information necessary for the purposes of the project, thus no improved information technology will be utilized.

A.4 Efforts to Identify Duplication and Use of Similar Information

An extensive review of scientific literature was conducted to identify previous studies of exposure to air pollution by vehicle occupants while on public highways. Although a few studies were identified, the current study builds upon previous work by expanding the number of measured health outcomes, by performing a more intense characterization of pollution exposure (e.g. more thorough chemical speciation of particulate pollutants), by examining a more inclusive study population (previous studies tend to focus on professional drivers rather than daily commuters), and by increasing statistical power by including a larger number of study participants.

A.5 Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

If this data is not collected or is collected less frequently, we will not be able to assess the public

health impacts of exposure to air pollution while commuting on highways.

There are no legal obstacles to reduce the burden of this data collection. The number of responses for study participants is described in Table A.12-1.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection complies with the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60 Day Federal Register Notice was published in Federal Register Vol. 74, No. 104 /6/2/2009, pages 26404-26406. A copy of the announcement is in Attachment 2. No public responses were received.

B. The following individuals were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements to be recorded and reported:

Fuyuen Yip, PhD, MPH
Air Pollution Respiratory Health Branch/EHHE/NCEH/CDC
Phone: 770.488.3719
fyip@cdc.gov

Tegan Boehmer, PhD, MPH
Air Pollution Respiratory Health Branch/EHHE/NCEH/CDC
Phone: 770.488.3714
tboehmer@cdc.gov

Jeremy Sarnat, Sc.D.
Rollins School of Public Health, Emory University
Phone: 404-712-9725
jsarnat@emory.edu

Roby Greenwald, Ph.D.
Rollins School of Public Health, Emory University
Phone: 404-727-4620
roby.greenwald@emory.edu

Cherry Wongtrakool, M.D.
Emory School of Medicine
Phone: 404-727-5283
cwongtr@emory.edu

A.9 Explanation of Any Payment or Gift to Respondents

Participation in this study requires approximately 6-7 hours of the subject's time. Study participants will receive a token of appreciation of $150 for each 27-30 hour period from pre-commute monitoring until the end of completed commute and health monitoring. The maximum amount provided to any one study participant is $300. If the participant does not finish the study, then they will be provided a token of appreciation for the visits that they have completed.

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. In the review of this application, it has been determined that the Privacy Act is applicable. The applicable system of records notice is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." Identifying information is necessary to facilitate the personal contact with respondents required to conduct the survey. The identifying information will remain with investigators at Emory University and will not be forwarded to CDC; however because Emory is a contractor for CDC and would have the link between name and ID number, the Privacy Act applies. The principal investigator from Emory University will keep, in a secure location, study documents containing individual identifiers and the link between name and study id number.

B. IIF will be collected, along with the personal information regarding each individual's history of cardiovascular and respiratory illnesses. IIF is necessary to facilitate the personal contact with respondents required to conduct the survey. However, IIF will be left with Emory University and will not be forwarded to CDC. Hard copies of questionnaires used for data entry at CDC will be identified by ID number only.

The paper documents containing personal identifiers will be kept in locked file cabinets at Emory University, and computer files will be password-protected and access will be limited to authorized study personnel. All staff working on the project will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes. Responses in published reports will be presented in aggregate form, and no individuals will be identified by name.

C. Written consent will be obtained from study participants before they participate in any study activities.

D. Participation in the study will be voluntary.

45 CFR 46 (Regulations for Protection of Human Subjects) apply to this project. The protocol has been approved by the Emory University Institutional Review Board (Attachment 6: IRB renewal for 2010-11 has been submitted) and CDC Human Subjects Office has made the determination that CDC is not engaged and a reliance agreement is not necessary.

A.11 Justification for Sensitive Questions

Questions of a highly sensitive nature will not be asked, nor will social security numbers be requested. Questions on smoking, stress level, and diagnosis of cardiovascular or respiratory illness may be considered by some respondents to be sensitive, but most people do not find it highly sensitive. It is very important to ask these questions to ensure that all possible confounding factors are considered in our analysis so that a clearer relationship between in-vehicle exposures and health outcomes can be assessed. These data will also assist us in translating data into public health practice. Respondents will be informed that participation in the study is voluntary and they may refuse to answer any of the questions.

OMB considers questions of race/ethnicity to be of a sensitive nature. Studies sponsored by CDC routinely collect this information to assist researchers in translating data from studies into public health practice. Again, respondents are told that participation in the study is voluntary and they may refuse to answer any of the questions.

A.12 Estimates of Annualized Burden Hours and Costs

Type of Respondent	Form Name	No. of Respondents	No. Responses/ Respondent	Average Burden per Response (in hours)	Total Burden Hours
Eligible participants with and without asthma	Baseline questionnaire	40	1	20/60	13
Eligible participants with and without asthma	Symptom diary	40	5	2/60	7
Eligible participants with and without asthma	In-vehicle data collection during scripted commute	40	2	2	160
	Total				180

A.12 - 2 Total Annualized Costs to Respondents

The average hourly wage in 2008 in the five largest counties of the Atlanta metropolitan region (Fulton, Gwinnett, Cobb, Dekalb, and Clayton) was $24.96 (calculated as the average weekly wage divided by 40 hours). This data is from the Georgia Department of Labor and summarized in a report published online at: http://explorer.dol.state.ga.us/mis/Current/ewcurrent.pdf

Type of	Number of	Average	Total	Hourly	Total

Respondents	Respondents	Burden per Respondent (in hours)	Burden Hours	Wage Rate	Respondent Costs
All study participants	40	4.5	180	$24.96	$4493
Total					$4493

A.13 Estimates of Other Annualized Respondent Capital and Maintenance Costs

There are no other annualized respondent capital and maintenance costs.

A.14 Estimates of Annualized Cost to the Federal Government

Costs are for 10% effort of two CDC personnel and the contractual costs associated with conducting field data collection for one year. All costs were based on experience with field studies.

Item	Total Cost	Annualized Cost
Salary (personnel costs of fed. employees involved in planning and analysis)	$16867	$16867
Fringe (20%)	$3373	$3373
Contractual services to collect data (including fringe and indirect costs)	$148941	$148941
Subtotal	$169184	$169184
CDC Administrative (15%)	$22341	$22341
Total	$191522	$191522

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis Plan

Analyses will be conducted to examine both the exposure assessment and epidemiologic hypotheses. The data analysis plan includes descriptive statistics (mean, standard deviations, and distribution percentiles) of in-vehicle pollutant levels for the commutes, including differences among subjects and vehicles and correlations among in-vehicle pollutant concentrations. Specific attention will be given to examining the association between in-vehicle pollutant levels and ambient pollutant concentration measurements at a central monitoring site.

Mixed effect regression models will examine the hypothesis that associations between in-vehicle pollutants and acute cardiorespiratory responses occur as a result of same-day exposures during the prescribed commute. Blood-based health measurements will be collected twice per commuting period for each subject: once just prior to the commute, and once approximately 1

hour after the commute. Other health-related measurements will be made at multiple lag times following the commute. For each of these variables, the difference between each subject's pre-commute and post-commute measurements will be used as an outcome variable in a mixed effects model. Our initial model treats the in-vehicle values as fixed effects to establish baseline associations. Confounders include:

- ambient pollutant concentrations measured at central sites;
- PM2.5 measured during pre-commuting periods with the continuous monitors;
- in-vehicle noise levels;
- subject heart rate and self-reported stress levels and
- ambient temperature and relative humidity.

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Baseline data collection for new participants	0.5-6 months after OMB approval
Data collection	1-12 months after OMB approval
Analysis of data	1-15 months after data collection
Publication	15-18 months after data collection

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

OMB approval to not display the expiration date is not being sought.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certifications.

B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

The target population for this study includes who commute to work by automobile in the Atlanta metropolitan region.

In-vehicle air quality data will be collected using a variety of real-time and time-integrated (filter-based) techniques. Measured health outcomes include spirometry data (forced expiratory volume in one second, forced vital capacity), exhaled nitric oxide, exhaled breath condensate, heart rate and heart rate variability data, oximetry data, and measurements of blood cytokines and other inflammatory or pro-thrombotic biomarkers. We plan compare these endpoints to those measured at baseline as well as to conduct these measurements at set time-points following the exposures to create a time series. We also plan to compare changes between exposures conducted at different times of year.

Power calculations for selected *a priori* hypotheses of interest were conducted using Rochon's non-central Wald χ^2 approximation for repeated measures experiments. $PM_{2.5}$ concentrations were randomly sampled (with 100 replicates) for 40 subjects from historical records of ambient PM2.5 concentrations at four monitoring stations in Atlanta during 1999 to 2003. $PM_{2.5}$-mediated health effect estimates and health measure variances were taken from Riediker *et al.* [27]. Estimates of within-subject correlations in health measurements are presented for both "moderate" and "weak" correlation scenarios, in order to determine their predicted effects on statistical power. The "moderate" correlation scenario assumes a correlation of 0.5 between health measurements taken on different days in the same subject and a correlation of 0.8 between health measurements taken a few hours apart on the same day in the same subject, after adjustment for pollutant exposures and other predictors. The "weak" correlation scenario is similar, but assumes a correlation of 0.2 for measurements on different days and 0.5 for measurements on the same day. Power estimates (with a sample size of 40) for most measurements under the "moderate" correlation scenario exceed 0.99 and exceed 0.96 for the "weak" correlation scenario.

B.2 Procedures for the Collection of Information

We have collected, and will continue to collect, health information using questionnaires, spirometry, exhaled breath tests, Holter monitoring (heart rate and heart rate variability) and collection of blood samples for analysis of cytokines and other biomarkers. We will conduct pulmonary function tests using spirometry instruments. The important measurements include forced vital capacity (FVC) or the greatest volume of air exhaled from a maximal inspiration to a complete exhalation; the forced expiratory volume in one second (FEV_1) or the volume of air exhaled in the first second of a FVC maneuver; and the ratio between these two values: FEV_1/FVC. During the test, it is critical that participants are properly coached to exert the maximum effort possible. The individuals who administer the spirometry tests were trained to conduct the test and properly coach study participants. Holter monitors will be attached to study subjects by personnel trained in their use in a gender-specific manner. Blood samples will be collected by trained phlebotomists.

Quality Control Procedures

The questionnaires are administered by trained interviewers. Data coding and preparation will be done by the principal investigator and staff at Emory University. Instrumentation will be evaluated for performance at the beginning and end of each exposure by experienced personnel. When appropriate, field blanks will be collected for the assessment of background levels of measured values.

B.3 Methods to Maximize Response Rates and Deal with Non-response

In the context of this study, "response rate" is defined as the percentage of subjects meeting our eligibility criteria who consent to participate and complete the study activities. As part of the consent process prior to enrollment, all subjects will be informed of the number of hours required to complete the study as well as the number and types of moderately-intrusive health measurements that will need to be performed. Recruits who decline to participate prior to enrollment will not be considered non-responsive. Only recruits who provide informed consent and undergo initial baseline characterization and subsequently withdraw before protocol completion will be considered non-responsive. In a previous exposure study involving a similar number of hours of subject participation, only 5% of subjects who began the protocol withdrew before completion. We expect a similar response rate for this study.

B.4 Test of Procedures or Methods to be Undertaken

All study materials have been evaluated in pilot tests involving nine or fewer respondents.

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

CDC Investigators:

PI: Fuyuen Yip, PhD, MPH
Air Pollution Team Lead
Air Pollution Respiratory Health Branch/EHHE/NCEH/CDC
4770 Buford Highway NE, MS F58
Atlanta, GA 30341
Phone: 770.488.3719
fyip@cdc.gov

Tegan Boehmer, PhD, MPH
Epidemiologist
Air Pollution Respiratory Health Branch/EHHE/NCEH/CDC
4770 Buford Highway NE, MS F58
Atlanta, GA 30341
Phone: 770.488.3714
tboehmer@cdc.gov

Emory University Investigators:

PI: Jeremy Sarnat, Sc.D.
Assistant Professor
Department of Environmental and Occupational Health
Rollins School of Public Health
Emory University
1518 Clifton Road
Atlanta, GA 30322
Phone: 404-712-9725
jsarnat@emory.edu

Roby Greenwald, Ph.D.
Research Assistant Professor
Department of Environmental and Occupational Health
Rollins School of Public Health
Emory University
1518 Clifton Road
Atlanta, GA 30322
Phone: 404-727-4620
roby.greenwald@emory.edu

Cherry Wongtrakool, M.D.
Assistant Professor
Emory School of Medicine
Division of Pulmonary, Allergy and Critical Care
Whitehead Biomedical Research Building
615 Michael Street, Suite 205
Atlanta, GA 30322
Phone: 404-727-5283
cwongtr@emory.edu

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Attachments

Attachment 1 Section 301 of the Public Health Service Act (42 USC 241)
Attachment 2 Federal Register Notice
Attachment 3 Pulmonary Health Questionnaire
Attachment 4 Symptom Diary
Attachment 5 Summary of In-Vehicle Data Collected During Scripted Commute
Attachment 6 Emory University IRB Approval