Information Collection Request

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

Supporting Statement B

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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

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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