

## HEALTH EFFECTS INSTITUTE

### REQUEST FOR QUALIFICATIONS AND PROPOSAL FOR QUALITY ASSURANCE OVERSIGHT

**July 13, 2017**

#### SUMMARY

**The Health Effects Institute (HEI) is seeking qualified contractors to provide quality assurance services for two research studies on air pollution and health.**

#### BACKGROUND

The mission of HEI is to provide high-quality, impartial, relevant scientific information on the health effects of pollutants from motor vehicles and other sources in the environment. As accurate scientific conclusions are dependent on the validity of the underlying data and the precision with which it is reported, HEI uses third-party quality assurance (QA) oversight for most research projects involving human subjects and other projects with a high potential for use in regulatory decisions. These procedures augment the general QA/QC procedures applied to all HEI studies (through staff and Committee oversight) and provide assurance that data are collected under defined conditions and are reliable and traceable through analyses. One important feature of the HEI special QA oversight is auditing the data presented by the investigator in the Final Report. A description of HEI Research and Review Processes and QA Policies and Procedures are enclosed (see Attachments 1 and 2).

Brief descriptions of the two individual studies including their current status and QA needs are described below.

#### **Study # 1: Air quality by genomics interactions in a cardiovascular disease cohort**

Investigators are examining the effects of acute and chronic air pollution exposure on cardiovascular disease using previously collected data from CATHGEN, a cohort of individuals undergoing coronary artery catheterization in North Carolina between 2001 and 2011 (n~9,300). For the HEI study, they are investigating:

1. the association of air pollution (PM<sub>2.5</sub>, ozone and mobile-source air pollution) with acute coronary artery disease (CAD) events and cardiovascular atherosclerotic disease state.
2. gene-by-air quality interactions on CAD acute events and cardiovascular disease state.
3. the role of air quality and air quality-by-gene interactions on emerging and newly discovered molecular biomarkers of CAD.

Location: Durham, NC

Principal Investigator: William Kraus, Duke University

Status: Final Report due 7/31/2017

QA needs: an off-site audit of the final report to ensure that the results provided in the final report are an accurate representation of the data analyzed.

**Study #2: Improvements in air quality and health outcomes among California Medicaid enrollees due to goods movement actions**

Investigators are examining the link between reductions in ambient air pollution from the implementation of the “Emissions Reduction Plan for Ports and Goods Movement” by the California Air Resources Board (CARB) in 2006 and subsequent improvements in health outcomes in about 23,000 California Medicaid fee-for-service (FFS) beneficiaries with chronic conditions in 10 CA counties. The specific aims of the study are to:

1. Develop and evaluate measures for health effects and time-varying confounding factors (e.g. change in disease severity) to support the proposed research.
2. Assess reductions in exposure to pollutants among Medicaid enrollees living in various areas by assigning previous developed land use regression models and compare the degrees of reduction in pollutant concentrations from the pre to the post-policy period.
3. Examine whether pollutant reductions resulted in improvements in health outcomes, including reduction in the number of emergency department visits, hospitalizations, and doctor visits among Medicaid beneficiaries with asthma, CVD, COPD and diabetes by estimating the difference-in-differences using generalized linear multilevel models and sensitivity analyses.

Location: Los Angeles

Principal Investigator: Ying-Ying Meng, University of California – Los Angeles

Status: ongoing (start 11/1/2016: total duration 2 years)

QA needs: an on-site audit during year 2 to audit data used for the exposure and health effects analyses, and an off-site audit of the final report. The duration of the on-site audit should not exceed 3 days (but could be shorter).

**OBJECTIVE OF THIS REQUEST**

The objective of this Request is to:

1. Solicit statements of qualifications (Phase 1)
2. Request proposals for auditing HEI-funded research studies (Phase 2)

**INSTRUCTIONS FOR PREPARING THE APPLICATION**

Interested teams may apply for QA oversight of one or both studies. The application consists of two phases.

**Statement of Qualifications (Phase 1)**

Interested applicants should submit to HEI the following: a) a statement of qualifications including a list of QA work that has been done during the last five years and that is relevant to the HEI studies, b) curriculum vitae of the key personnel involved and c) specify which study they are interested in auditing, and d) list any actual or potential collaborations with the study investigators. More details about the studies and the composition of each study team can be found at <https://www.healtheffects.org/research/ongoing-research>

Preferred areas of team expertise necessary to conduct these audits include:

- Epidemiologic expertise, including experience with genome-wide association studies and use of administrative databases
- Statistical expertise, including multilevel modeling and
- Air pollution exposure measurement and modeling including experience with satellite data, and land use regression modeling.

HEI will review the qualifications of the applicants and select those whose qualifications appear to be most relevant to the research for the second phase of the application process. The statement of qualification is non-binding.

The deadline for responding to Phase 1 is August 15, 2017. Applicants will be informed whether or not to submit a proposal within 1 week after the submission date.

### **Request for proposals (Phase 2)**

Selected applicants will be asked to submit a written proposal for QA oversight, which should include for each study: a) a proposed scope of work, b) a schedule and detailed list of tasks for the audits and hours allocated to each task, c) a list of personnel involved and their responsibilities, and d) a budget estimate with separate items for personnel costs (indicating the number of hours and the hourly rate of each member of the QA team) and travel costs. (Please note that HEI does not pay for travel time; however, travel time can be billed if it is used for work related to the visit). HEI will provide additional relevant material (e.g., project plans, progress reports) to the selected applicants.

The deadline for responding to Phase 2 is September 30, 2017. HEI staff will review the proposals based on the quality of the QA plan, expertise of the team, and reasonableness of the proposed costs. A response to all applicants will be provided by October 15, 2017.

### **TO APPLY**

Complete sections of the application as described above. No specific format is required. Please direct all correspondence and submissions to Dr. Hanna Boogaard by email, [jboogaard@healtheffects.org](mailto:jboogaard@healtheffects.org).

### **ATTACHMENTS**

1. HEI Research and Review Processes, revised April 2016
2. HEI Quality Assurance Policies and Procedures, revised April 2016