HEALTH EFFECTS INSTITUTE

REQUEST FOR QUALIFICATIONS AND PROPOSAL FOR QUALITY ASSURANCE OVERSIGHT

March 31, 2016

SUMMARY

The Health Effects Institute (HEI) is seeking qualified contractors to provide quality assurance services for studies investigating the adverse health effects of low levels of air pollution.

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 Procedures for Quality Assurance and Quality Control is enclosed (see Attachments 1 and 2).

BRIEF DESCRIPTION OF THE STUDIES COVERED BY THIS RFQP

The studies in this RFQP for QA were selected from RFA 14-3, "Assessing adverse health effects of long-term exposure to low levels of ambient air pollution" (see Attachment 3).

1. Dr. Francesca Dominici, Harvard School of Public Health, and colleagues will assess adverse health effects of long-term exposure to low levels of air pollution in the US using Medicare and Medicaid data. In total they have a study population of about 56 million Americans. They will develop hybrid air pollution exposure models including satellite data, chemical transport models, land use and weather variables, and routinely collected monitoring data. They will investigate time to hospitalization by cause, disease progression (time to re-hospitalization), and time to death. They will develop and apply new causal modeling methods to estimate exposure-response functions adjusting for confounding and exposure measurement error. Finally, they will develop tools for reproducible research including approaches for data sharing, record linkage, and statistical software.
2. Dr. Mike Brauer, University of British Columbia, and colleagues will assess all cause and cause-specific mortality effects of long-term exposure to low levels of air pollution in Canada using Canadian census data. In total, they will have a study population of about 6.4 million Canadians. They will develop hybrid models using primarily satellite data, although chemical transport models, land use variables, and routinely collected monitoring data are included as well. Indirect adjustment approaches will be developed

for missing risk factors such as smoking. The shape of the exposure-response function will be characterized using newly developed flexible non-linear exposure-response functions.

3. Dr. Bert Brunekreef, University of Utrecht, Netherlands, and colleagues will assess adverse health effects of long-term exposure to low levels of air pollution in Europe using pooled data from 10 existing cohort studies with detailed individual data (~340,000 participants). In addition, they will analyze 6 administrative cohorts with less detailed data in a study population of ~25 million Europeans. They will develop hybrid European wide and local air pollution exposure models using land use and traffic data, satellite data, and dispersion model estimates. They will investigate all cause and cause-specific mortality, lung cancer incidence, and incidence of coronary and cerebrovascular events.

OBJECTIVE OF THIS REQUEST

The objective of this Request is to request proposals for providing QA services for these three studies based on the following plan:

Preparatory work
The audit team will review SOPs and data management plans from each study in preparation for the initial QA site audit (see below).

QA audits
A minimum of two site visits for each study site is anticipated. Additional work may involve audits conducted by phone or by review of paper records or computer files.

A first QA audit to each study site will be conducted during the second year of the study to audit a subset of the data used for the health effects analyses. Depending on the outcome of this visit a follow-up visit may be scheduled (not to be included in the budget proposal). The duration of on-site audits should not exceed 3 days (but could be shorter).

A final off-site QA audit of each study will be conducted after submission of the final report to ensure that the results provided in the final report are an accurate representation of the raw data analyzed.

INSTRUCTIONS FOR PREPARING THE APPLICATION

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

1. **Letter of Intent**.
   The Letter of Intent should express the intention of applying and provide a tentative list of studies to be included in the application. Project plans for the studies will be sent upon receipt of the letter of intent. The letter of intent is non-binding and an applicant could request all the project plans and narrow down the choice when preparing the Application.

2. Application

The application shall consist of three components.

Statement of Qualifications. Interested applications should submit:

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 study and a description of how the team qualifications are relevant to objectives of this RFQP
b) curriculum vitae of the key personnel involved
c) list any actual or potential collaborations with the study investigators

Although HEI will give preference to multidisciplinary teams, it is not expected that all members of the team will participate in every on-site QA audits as some of the data review may be conducted electronically.

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

a) epidemiologic expertise, including experience with use of administrative databases
b) statistical expertise, including experience with Cox proportional hazard models and, preferably with causal inference methods
c) air pollution exposure modeling including experience with satellite data, land use, chemical transport models as well as air pollution dispersion models

Proposal for QA Oversight. The proposal should include:

a) the list of studies to be audited
b) a proposed scope of work for each study audits
c) a list of personnel involved and their responsibilities

Proposed Budget

The budget should itemize the personnel costs (indicating the number of hours and the hourly rate of each member of the QA team), including time for preparation, on-site audit and report writing. (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). No travel costs should be provided at this time: an estimate of those costs will be requested only from the selected QA team.

TO APPLY

Complete sections of the application as described above. No specific format is required. For questions, please contact Dr. Hanna Boogaard, e-mail jboogaard@healtheffects.org.

Due dates

A letter of intent should be submitted electronically by **May 31, 2016.** Project plans for the three studies will be sent upon receipt of the letter of intent.

The application should be submitted in electronic form by **August 31, 2016.**

Please direct all correspondence to Dr. Hanna Boogaard, email jboogaard@healtheffects.org.

REVIEW OF QA APPLICATIONS

HEI will review the applications based on the quality of the QA Proposal (such as a description of the audit objectives and evidence of understanding of the level and extent of data audit needed), expertise of the team, and reasonableness of the proposed costs. A response to all applicants will be provided by **September 30, 2016.**

ATTACHMENTS

1. HEI Research and Review Processes
2. Quality Assurance /Quality Control Procedures for HEI Funded Studies
3. RFA 14-3