HEALTH EFFECTS INSTITUTE

REQUEST FOR QUALIFICATIONS AND PROPOSAL
FOR QUALITY ASSURANCE OVERSIGHT

<mark>July 2020</mark>

SUMMARY

The Health Effects Institute (HEI) is seeking qualified contractors to provide quality assurance services for thirteen 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 air pollution. 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. Unless otherwise specified, the HEI special QA oversight entails two audits, one during the course of the study and one of the data presented by the investigator in the HEI Final Report. Generally, the QA audit during the course of the study is conducted on-site (the duration should not exceed 2 days), and the QA audit of the final report is conducted remotely. A description of HEI Research and Review Processes and Quality Assurance / quality control procedures for HEI studies are enclosed (see Attachments 1 and 2).

Brief descriptions of the individual studies including their current status and QA needs are described below. More details about the studies and the composition of each study team can be found at https://www.healtheffects.org/research/ongoing-research

DESCRIPTION OF STUDIES NEEDING QA OVERSIGHT

RFA 18-1, "Assessing Improved Air Quality and Health from National, Regional, and Local Air Quality Actions"
For almost two decades, HEI has played a leadership role in accountability research, to assess whether actions to improve air quality have been effective in improving public health. HEI is now embarking on a third wave of studies solicited in December 2018 under request for applications (RFA) 18-1, "*Assessing Improved Air Quality and Health from National, Regional, and Local Air Quality Actions*." These four studies are summarized below (Studies 1-4).

Study #1: Assessing the National Health and Educational Benefits of the EPA's School Bus Retrofit and Replacement Program: A Randomized Controlled Trial Design
The investigators will study the National Clean Diesel Rebate Program, a lottery program that allocates available funding to school districts across the United States to replace or retrofit old-technology diesel powered school buses. Adar and colleagues will compare student health and educational performance in districts with and without such funding. The investigators plan to analyze student attendance rates and emergency department visits for respiratory causes in the

school-aged Medicaid population, as well as standardized test scores for math and English among children in grades 3 through 8. Approximately 400 districts with 1.5 million students that received funding will be compared with about 2,700 districts that were not selected in the lottery since the program began in 2012.
Location: Ann Arbor, Michigan
Principal Investigator: Sara Adar, University of Michigan School of Public Health
Duration: 3 years
Start date and anticipated end date: 1/1/2020 to 12/31/2022
Status: middle of Year 1
QA needs: an off-site audit of the final report

Study # 2: Impacts of Vehicle Emission Regulations and Local Congestion Policies on Birth Outcomes Associated with Traffic Air Pollution
The investigators will assess effects of emission-control measures on birth outcomes associated with traffic-related air pollution in Texas. Hystad and colleagues will evaluate air quality changes associated with national motor vehicle emissions regulations, as well as a diverse array of local congestion reduction programs implemented in Texas over the past 25 years. The investigators plan to use a combination of economics and epidemiology approaches to analyze existing data from a population-based cohort of 7.6 million births in Texas from 1996–2016.
Location: Corvallis, OR
Principal Investigator: Perry Hystad, Oregon State University
Duration: 3 years
Start date and anticipated end date: 4/1/2020 to 3/31/2023
Status: beginning of Year 1
QA needs: an on-site audit during year 2 to audit data used for the exposure and health analyses, and an off-site audit of the final report

Study # 3 How Do Household Energy Interventions Work?
The investigators will focus on a coal ban and heat pump subsidy program in the Beijing region. They are building on an existing panel study that is following about 2,850 people who live in 50 villages around Beijing. Half the villages are subject to the policy, the other half are not. The investigators will collect air quality measurements in all villages during the heating seasons and collect personal exposure monitoring data from approximately half of the study participants. They plan to compare data on respiratory symptoms and cardiovascular biomarkers in people in the villages where the policies are in place with those living in control villages. They are interested in evaluating changes in the chemical composition of fine particles from different pollution sources and analyze their contribution to the health outcomes, with a focus on household coal burning.
Location: Montreal, QC, Canada
Principal Investigators: Sam Harper and Jill Baumgartner, McGill University
Duration: 3 or 4 years
Start date and anticipated end date: 5/1/2020 to 4/30/2023 or 4/30/2024
Status: beginning of Year 1
QA needs: an on-site audit during year 2 to audit data used for the exposure and health analyses, and an off-site audit of the final report

Study # 4: Accounting for the health benefits of air pollution regulations in China, 2008-2020

The investigators will evaluate the major national regulatory policies that were implemented in China from 2008–2018. They will focus on regulations in particular regions that target specific sources, such as coal combustion, and how they have reduced ambient concentrations of fine particles. They plan to analyze trends in mortality using data from two nationwide cohorts of Chinese adults maintained by the China Centers for Disease Control, using two complementary approaches: chemical transport models and empirical source apportionment analyses: the Chinese Longitudinal Healthy Longevity Survey (CLHLS) cohort and a cohort draw from two rounds of the China Chronic Disease and Risk Factors Surveillance (CCDRFS) survey.

Location: Boston, MA
Principal Investigator: Patrick Kinney, Boston University
Duration: 3 years
Start date and anticipated end date: 6/1/2020 to 5/31/2023
Status: beginning of Year 1
QA needs: an on-site audit during year 2 to audit data used for the exposure and health analyses, and an off-site audit of the final report

RFA 19-1, "*Applying Novel Approaches to Improve Long-Term Exposure Assessment of Outdoor Air Pollution for Health Studies*"

There are many challenges in conducting epidemiological studies of long-term exposure to air pollutants given that concentrations vary so widely over space and time. One difficulty is how to accurately determine the exposures of individuals to air pollution. Another is how to quantify the influence of exposure measurement error on health-risk estimates. HEI is embarking on studies to enhance exposure assessment that were funded under request for applications (RFA) 19-1, "*Applying Novel Approaches to Improve Long-Term Exposure Assessment of Outdoor Air Pollution for Health Studies*." These five new studies are summarized below (studies 5-9).

Study #5: Accounting for Mobility in Air Pollution Exposure Estimates in Studies on Long-Term Health Effects

The investigators aims to evaluate the contribution of individual mobility in air pollution exposure estimates. They will use location tracking on a mobile phone application for 2,000 individuals in the Netherlands and Switzerland. These data, together with available data on air pollutant concentrations, will then be used to estimate long-term hourly exposure estimates. Subsequently, these exposure estimates will be compared against exposures estimated using home addresses. The team will then apply their findings to three major cohorts:— the Study on Air Pollution and Lung Disease in Adults (SAPALDIA) in Switzerland, participants in the European Prospective Investigation into Cancer and Nutrition Netherlands (EPIC-NL), and the Swiss National Cohort.

Location: Basel, Switzerland
Principal Investigator: Kees de Hoogh, Swiss Tropical and Public Health Institute
Duration: 3 years
Start date and anticipated end date: 6/1/2020 to 5/31/2023
Status: beginning of Year 1
QA needs: an off-site audit of the final report

Study # 6: Spatial Statistical Learning Methods for Estimating Ambient Air Pollution
The investigators will prepare maps of modeled annual average air pollution maps across the Netherlands, validate the estimates maps using new measurements from over 100 sites across the Netherlands, and evaluate the performance of several exposure models. For example, they plan to use measurements from low–-cost sensors, mobile monitoring, and a national network of air pollution monitors. They will conduct cross-comparisons to evaluate how different exposure assessment methods compare in their ability to predict long-term pollutant concentrations, with a particular focus on spatial variability of pollutants. Furthermore, the various models will also be applied to three cohorts in the Netherlands to evaluate how they various models influence health effect estimates in epidemiological studies: the Dutch Environmental Longitudinal Study (DUELS), Prevention and Incidence of Asthma and Mite Allergy (PIAMA) study and EPIC-NL.
Location: Utrecht, Netherlands
Principal Investigator: Gerard Hoek, Utrecht University
Duration: 3 years
Start date and anticipated end date: 6/1/2020 to 5/31/2023
Status: beginning of year 1
QA needs: an off-site audit of the final report

Study # 7: Investigating the Consequences of Measurement Error of Gradually More Sophisticated Long-Term Personal Exposure Models in Assessing Health Effects: The London Study (MELONS)
The study team will investigate the consequences of measurement error on estimates of health effects of long-term exposure to outdoor air pollution in London by developing increasingly sophisticated exposure models. They plan to compare exposure models that account for mobility, are based on exposure estimates at the residential address, and are based on concentrations measured at the nearest air pollution monitor. The air pollution surfaces will include outputs from several types of air pollution models (a chemical transport model (CMAQ-urban), land use regression, and machine learning), and combinations of these models. Finally, exposures will be applied to the London segment of the UK Biobank study to evaluate associations with asthma, chronic obstructive pulmonary disease, myocardial infarction, stroke incidence, and mortality.
Location: London, United Kingdom
Principal Investigator: Klea Katsouyanni, Imperial College London
Duration: 3 years
Projected Start date and anticipated end date: 9/1/2020 to 8/31/2023
Status: Pending
QA needs: an off-site audit of the final report

Study # 8: Optimizing Exposure Assessment for Inference about Air Pollution Effects with Application to the Aging Brain
The investigators will compare and contrast scientific and logistical benefits of different approaches to air pollution exposure assessment for cohort studies. They will leverage large air pollution datasets obtained from low-cost sensors, mobile monitoring, and passive samplers. The exposure assessment approaches will be applied to determine associations with cognitive decline and dementia incidence in an ongoing cohort study, Adult Changes in Thought Air Pollution

(ACT-AP). In particular, the investigators would like to use statistical techniques to assess the bias and precision of health effect estimates.
Location: Seattle, WA
Principal Investigator: Lianne Sheppard, University of Washington
Duration: 3 years
Projected Start date and anticipated end date: 9/1/2020 to 8/31/2023
Status: Pending
QA needs: an off-site audit of the final report

Study # 9: Comparing the Estimated Health Impacts of Long-Term Exposure to Traffic-Related Air Pollution Using Fixed-Site, Mobile, and Deep Learning Models
The investigators will evaluate health impacts of long-term exposures to traffic-related air pollution using exposure estimates from fixed-site and mobile measurement campaigns, as well as deep learning models, in Toronto and Montreal, Canada. They will compare exposure estimates generated by these models to present-day and historical measurements, and to each other. They plan to estimate concentration-response relationships for mortality in the Canadian Census Health and Environment Cohort (CanCHEC) and evaluate how the magnitudes and shapes of those relationships are influenced by different exposure models.
Location: Montreal, QC, Canada
Principal Investigators: Scott Weichenthal, McGill University
RFA: RFA 19-1 (exposure)
Duration: 3 years
Start date and anticipated end date: 5/1/2020 to 4/30/2023
Status: beginning of year 1
QA needs: an off-site audit of the final report

RFA 18-2, "Walter A. Rosenblith New Investigator Award"
HEI has established the Walter A. Rosenblith New Investigator Award to provide funding for outstanding investigators who are beginning independent research. By providing financial support for investigators at this early point in their careers, HEI hopes to encourage highly qualified individuals to undertake research on the health effects of air pollution. The two Rosenblith studies are described below (studies 10-11).

Study # 10: Air pollutants and the Gut Microbiota and Metabolome During Early Life: Implications for Childhood Obesity
The investigators will examine whether prenatal and/or early-life exposure to air pollutants affects the infant gut microbiota and fecal metabolome, thereby altering infant growth trajectories in the first two years of life. She plans to study this in an ongoing longitudinal cohort of Hispanic mother-infant pairs in California with existing validated clinical assessments of infant growth trajectories. She will also use gut microbial profiling and high-resolution fecal metabolomics profiles to understand the mechanisms underlying the obesogenic effects of air pollutants in early life.
Location: Boulder, CO
Principal Investigator: Tanya Alderete, University of Colorado Boulder

Duration: 3 years
Start date and anticipated end date: 5/1/2020 to 4/30/2023
Status: beginning of year 1
QA needs: an off-site audit of the final report

Study # 11 Air Pollution Exposure and Prefrontal Connectivity in Early Adolescence
The investigators will elucidate how fine-particle exposure affects the development of prefrontal connections and emotional behaviors during the transition from childhood to adolescence and whether this, in turn, contributes to greater risk for neuropsychiatric disorders. Using a novel hybrid spatiotemporal-exposure model, they will estimate annual average exposure to ambient fine particles of boys and girls across the United States who are participating in the Adolescent Brain Cognitive Development (ABCD) cohort. Investigators will then relate the fine-particle exposures to structural connectivity of the prefrontal cortex at ages 9 to 10 years, and to impairments in neuropsychiatric outcomes after 1 year of follow-up at ages 10 to 11 years.
Location: Los Angeles, CA
Principal Investigators: Megan Herting, University of Southern California
Duration: 3 years
Start date and anticipated end date: 3/1/2020 to 2/28/2023
Status: beginning of year 1
QA needs: an off-site audit of the final report

Other Funding Mechanisms
HEI has funded two studies under other funding mechanisms. One study (study 12) was funded under RFA 17-1, "*Assessing Adverse Health Effects of Exposure to Traffic-Related Air Pollution, Noise, and Their Interactions With Socio-Economic Status.*" The final study (study 13) was funded under RFA 17-2, "*Health Effects of Air Pollution*", which provides a mechanism for investigators whose area of interest falls outside of current RFAs, but is compatible with the HEI research program and mission. The two studies are described below.

Study #12 Intersections as hot spots: assessing the contribution of localized non-tailpipe emissions and noise on the association between traffic and children's health
Investigators will evaluate the adverse effects of non-tailpipe emissions and of noise on children's respiratory health. The investigators will build on the most recent cohort (Cohort E) from the Children's Health Study (CHS) in Southern California, recruited during 2002-2012, and with longitudinal data on asthma and lung function. They will develop a new exposure model for non-tailpipe PM metals using compositional data from existing PM filters, along with data on intersections and road slopes. The chemical analyses of these filters are a major component of the HEI study. They will use a dispersion model (CALINE) to estimate tailpipe exposure. For noise, they will use the Federal Highway Traffic Noise Model. In addition, they will assess several other factors, such as SES, green space, genetic ancestry, and stress. They will conduct cross sectional and longitudinal analyses of the data using various techniques including multi-level modeling.
Location: Los Angeles, CA
Principal Investigator: Meredith Franklin, University of Southern California

RFA: RFA 17-1 (traffic and health)
Duration: 4 years
Start date and anticipated end date: 6/1/2018 to 5/31/2022
Status: beginning of Year 3
QA needs: an off-site audit of the final report

Study #13 Quantifying Marginal Societal Health Benefits of Transportation Emission Reductions in the United States and Canada
Investigators propose a health impact assessment study of the benefit per ton of decreased emissions of NOx, SO2, NH3, primary PM2.5, and volatile organic compounds. They will assess the benefits based on averted mortality due to reduced PM2.5, O3, and NO2 exposure in the United States and Canada. This will be done for mobile and other sources using a new extension the investigators have built for the Community Air Quality Modeling System (CMAQ-adjoint) on a 12-km grid and the year 2014. Sensitivity and uncertainty analyses will include concentration-response functions, choice of health endpoint and valuation method, and spatial resolution of the air quality model. The investigators will also estimate per vehicle damage and create web-based and downloadable user interfaces to disseminate the data generated in the project.
Location: Ottawa, ON, Canada
Principal Investigator: Amir Hakami, Carleton University
Duration: 2.5 years
Start date and anticipated end date: 10/1/2018 to 3/31/2021
Status: end of year 2
QA needs: an off-site audit of the final report

APPLICATION PROCESS
The application process consists of 2 phases:
1. Statement of qualifications (Phase 1)
2. Proposal for auditing HEI-funded research studies (Phase 2)

INSTRUCTIONS FOR PREPARING THE APPLICATION

Interested teams may apply for QA oversight of one or multiple studies.

Statement of Qualifications (Phase 1)
Interested applicants should submit a statement of qualification using Form 1.The Statement should include 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 studies the QA team are interested in auditing, and d) list any actual or potential collaborations with the study investigators.

Preferred areas of team expertise necessary to conduct these audits include:
- Epidemiologic expertise, including experience with use of administrative databases
- Statistical expertise, including Cox proportional hazard models, regression, multilevel modeling and, preferably with machine learning techniques and causal inference methods.
- Air pollution exposure measurement and modeling including experience with low-cost sensors, satellite data, dispersion models 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 qualifications is non-binding.

Deadline: October 15, 2020. Applicants will be informed whether or not to submit a proposal and for which studies, within 2 weeks after the submission date.

Request for proposals (Phase 2)
Selected Phase 1 applicants will be asked to submit a written proposal for QA oversight for the specific studies using Form 2. The proposal 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 for each study 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, if applicable (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.

Deadline: December 15, 2020. 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 January 15, 2021.

Please use the specific Forms 1 and 2 www.healtheffects.org/sites/default/files/Statement-of-Qualification-Form2018.docx and www.healtheffects.org/sites/default/files/Request-for-Proposal-Form2018.docx.

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

ATTACHMENTS

HEI Quality Assurance / quality control procedures for HEI studies
https://www.healtheffects.org/research/quality-assurance

HEI Research and Review Processes:
https://www.healtheffects.org/research/research-and-review-processes

Current Investigators (with information on study oversight, progress reports, etc.)
https://www.healtheffects.org/research/investigators/commitments