RFA 21-1: QUANTIFYING REAL-WORLD IMPACTS OF NON-TAILPIPE PARTICULATE MATTER EMISSIONS

INTRODUCTION

With reductions in tailpipe particulate matter (PM) emissions, there is increasing interest in non-tailpipe emissions of PM from motor vehicles, specifically from tire, brake, and road wear and resuspension of road dust, and such emissions have not been sufficiently studied or characterized. HEI published a Request for Applications (RFA) on this topic in 2014 and funded one study that collected and analyzed samples at locations at the side of interstate and state highways around Boston (Health Effects Institute 2014). Study results were described in a series of papers in a special issue of the *Journal of the Air & Waste Management Association* (Huang et al. 2021; Koutrakis and Greenbaum 2021; Lawrence et al. 2021; Martins et al. 2021; Silva et al. 2021). This area continues to be of interest to HEI as described in its Strategic Plan 2020–2025 (Health Effects Institute 2020 p. 42).

BACKGROUND AND RATIONALE

Over the last few decades, there have been important legislative actions in various countries focused on control of tailpipe emissions, but non-tailpipe emissions into ambient air are not regulated. As a result, substantial reductions have been achieved for tailpipe emissions, and the increased relative contribution of non-tailpipe emissions to ambient PM concentrations is now beginning to receive more attention.

In contrast with particles in tailpipe emissions from on-road vehicles that are formed during the combustion process, non-tailpipe PM emissions are formed from mechanical abrasion and concurrent heat and evaporation. Main sources of these non-tailpipe emissions include brake and tire wear, road surface abrasion, and resuspended road dust. There are also contributions from wear of materials used to build roads, deterioration of vehicle materials (e.g., wheel weights and chassis rusting), and dust from surrounding areas. The particles from non-tailpipe sources differ from particles in tailpipe emissions both in composition and size distribution: their size is generally larger than tailpipe particles (Liati et al. 2019; Lyu et al. 2020; Nosko et al. 2017), and they have a higher percentage of metals, such as copper (Cu), barium (Ba), iron (Fe), zinc (Zn), and strontium (Sr) (Amato et al. 2014; Denier van der Gon et al. 2013; Harrison et al. 2021; HEI Special Committee on Emerging Technologies 2011; Pant and Harrison 2013).

Cu and Ba have been used extensively as chemical markers for brake wear emissions in non-tailpipe emissions studies. Because of toxicity concerns for aquatic organisms, Cu and certain other chemical components are now being phased out of brake pads in the United States (U.S. EPA 2015). Early results indicate that these changes and differences in the brake assemblies (i.e., drum vs. disc) might affect the levels of airborne particle emissions during brake operation (e.g., Gerlofs-Nijland et al. 2019; Hagino et al. 2016; Lyu et al. 2020), although additional tests are needed to compare brake pads of different types that are currently in use and on the market. In the case of tire wear emissions, researchers have used elemental markers, such as Zn; organic molecular markers, such as benzothiazoles (Knight et al. 2020; Pant and Harrison 2013; Zhang et al. 2018); and tire tread polymers (Panko et al. 2019). The contribution of brake and tire wear to ambient PM has been estimated to be as low as a few percent to as high as 50% of total ambient PM near busy roadways (Beddows et al. 2015; Grigoratos and Martini 2014; Jeong et al. 2019; Padoan and Amato 2018; Panko et al. 2019), but the contribution varies greatly depending on the characteristics of the vehicles (including weight, brakes, and tires) and on driving and environmental conditions.

In recent years, several studies have characterized mass, particle number, and chemical characteristics of brake and tire wear particles, and some data are available on the potential health effects of exposure to non-tailpipe emissions (COMEAP 2020; Stafoggia and Faustini 2018). Most studies to characterize non-tailpipe emissions have relied on laboratory measurements that use chassis or brake dynamometers or on analysis of near-road samples. Recent work under the United Nations Particle Measurement Programme (PMP) has sought to design a standard method for testing brake wear particles. Teams that work with the PMP have reported a novel particle measurement set-up for on-road investigation of brake wear particles (Farwick zum Hagen et al. 2019) and a real-world braking cycle (Mathissen et al. 2019). Emissions models require these measurements to estimate and validate total non-tailpipe emissions of $PM_{2.5}$ to the air. For example, the MOVES3 model developed by U.S. EPA calculates braking emission rates based on the brake pad composition, number and type of brakes, front versus rear braking, and airborne fraction, while accounting for $PM_{2.5}$ and PM_{10} mass distribution, braking intensity, and light-duty versus heavy-duty vehicle class based on measurements of brake and tire wear emissions from individual vehicles from the 2000s and earlier (U.S. EPA 2020). The emissions model used in California (EMFAC) has similar inputs and has been updated to include recently collected brake emissions data from light and heavy duty vehicles (California Air Resources Board 2021). Upcoming versions of MOVES, EMFAC, and other emissions models will continue to be updated based on newer and more extensive measurements.

Even with recent progress, challenges remain in conducting real-world measurements of non-tailpipe emissions. Study of non-exhaust emissions is complex because the composition of brakes and tires is generally proprietary, constantly changing, and varies by vehicle market (e.g., Europe, Japan, or the United States) and applications (e.g., light vs. heavy duty vehicles, traditional vs. low rolling resistance tires, and new vs. retreaded tires). Furthermore, both brake and tire emissions can vary widely based on brake and tire materials, road surface material, vehicle type, driving behavior, traffic composition, and environmental conditions (OECD 2020; Padoan et al. 2018). Hybrid and electric cars create another variable: such cars might produce greater amounts of tire wear because they are heavier and have higher torque than internal combustion engine cars, although the use of regenerative braking would likely reduce both brake and tire wear because it would reduce slippage between surfaces (e.g., at the tire-road interface) (Beddows and Harrison 2021; Liu et al. 2021; Timmers and Achten 2018). Additionally, mixing of the various wear particles together and with combustion particles in the road environment makes the detailed characterization of particle origins challenging. For example, brake or tire particles can deposit on the road surface and then be resuspended as part of road dust. Road dust also includes road salt, biological components (such as pollen), chemicals from various non-transportation sources, and debris from various sources.

Despite these challenges in assessing real-world emissions, there continues to be progress in measuring toxicity of non-tailpipe PM and exposure and potential health effects of non-tailpipe PM in human populations (e.g., Baensch-Baltruschat et al. 2020; Habre et al. 2021). Two recent epidemiological studies showed that exposure to combined non-tailpipe emissions was associated with various adverse health effects, including hospitalizations, mortality, and low birth weight (Smith et al. 2017; Stafoggia and Faustini 2018). Additionally, some toxicological studies found that brake pad materials were an important source for PM toxicity (Gerlofs-Nijland et al. 2019; Puisney et al. 2018; Selley et al. 2020).

Separately, concerns about aquatic toxicity of Cu have driven actions in several US states, which in turn have led to a memorandum of agreement between the U.S. EPA and certain representatives of the automotive industry to reduce Cu, some other metals, and their compounds to less than 0.5% by weight in brake pad linings by 2025 (U.S. EPA 2015). In response to this memorandum, some brake pad manufacturers are also reducing the levels of certain components (e.g., Cu and Sb) of their products in other locations (e.g., Europe). In addition, 6PPD-quinone from tires is toxic to certain species of salmon and may have adverse effects on salmon fisheries (Blair et al. 2021; Tian et al. 2021). There have been fewer ecotoxicological and epidemiological studies specifically considering tire and road wear particles (i.e., as opposed to particles from brake pads or the combination of all non-tailpipe emissions). Recent reviews concluded that the current weight of evidence suggests low human health risk from tire and road wear particles in air but noted that data are scarce and recommended that additional health outcomes be analyzed (Baensch-Baltruschat et al. 2020; COMEAP 2020; Kreider et al. 2019).

Overall, emissions of non-tailpipe PM remain poorly understood, and important questions remain regarding emissions, exposure, and ultimately, potential health effects of non-tailpipe PM (Gerlofs-Nijland et al. 2019; Stafoggia and Faustini 2018). Thus, in November 2020, HEI convened a workshop to bring together researchers, regulators, and industry groups to review current knowledge and key questions and gaps related to best methods for characterizing emissions, measuring and modeling air quality, and conducting human exposure assessment of non-tailpipe emissions. Workshop participants identified research needs in several areas, as follows:

1. There is a need for improving characterization of non-tailpipe emissions. Brake dynamometer tests of $PM_{2.5}$ emissions with standardized drive cycles and instrumentation are being developed to measure emissions at the source and minimize the influence of certain problems (e.g., overheating of enclosed brakes) that have affected earlier measurement platforms. Extending these tests to include more detailed chemical analysis would be useful. For tire and road wear particles, controlled

laboratory-based systems could be expanded to include additional road surfaces to better understand how the road surface material affects the morphology, size, and total mass of the resulting dust particles (e.g., Dall'Osto et al. 2014; Kim and Lee 2018). A standardized laboratory-based or on-road test system to isolate the tire wear particles might also be useful and could be informed by ongoing efforts of government agencies (e.g., UK Department of Transport and California Air Resources Board).

2. There is a need for consensus on which measurements or combinations of measurements best represent non-tailpipe emissions for use in exposure and health studies. Individual chemical components that have been typically used for real-world measurements of non-tailpipe emissions have multiple sources and usually constitute a small fraction of the total non-tailpipe PM emissions with the contribution fraction varying by vehicle and location (Harrison et al. 2021). Additionally, the levels of key tracers that have been used in epidemiology studies (e.g., Cu from brake pads) are being reduced in new brake pad formulations, so new tracers will be needed. Although one organic marker of tire and road wear particles in ambient air (ISO/TS 20593:2017) has been applied in several studies (Kreider et al. 2019; Panko et al. 2019), additional roadside studies are needed to apply and compare multiple organic and inorganic markers that could be useful in epidemiological studies with many samples. Information on multiple organic and inorganic chemicals and particle composition and size distribution would be valuable with a view toward identifying appropriate exposure surrogates for emissions from brake and tire wear. Surrogates able to distinguish brake, tire wear, and road wear particles would be particularly valuable for a proper separation of $PM_{2.5}$ contributions.
3. There is a need to better characterize human exposures and health effects of non-tailpipe PM. Panel studies of susceptible populations might provide an opportunity to improve exposure characterizations, to identify appropriate tracers, and to assess the potential of those tracers to contribute to the few health studies underway. Exposure and health studies would need to consider the complexity of multipollutant aerosol mixtures combining tailpipe and non-tailpipe emissions with each other and with other sources of air pollution.

More information on the workshop and the presentation slides are available on the HEI website at https://www.healtheffects.org/meeting/virtual-workshop-non-tailpipe-particulate-matter-emissions-and-exposure. To share key findings of the workshop more broadly, HEI also held a public webinar as part of its 2021 Virtual Annual Conference in May 2021; recordings and slides from the webinar are available at https://www.healtheffects.org/meeting/annual-conference-2021.

RFA OBJECTIVES

The overall objective of RFA 21-1 is to develop, evaluate, and apply real-world exposure indicators of non-tailpipe PM emissions from motor vehicles and to assess the impacts of such emissions on air quality, human exposure, and human health. The specific objectives of this RFA are as follows:

1. Identify and validate exposure indicators to characterize non-tailpipe PM emissions (e.g., from tire, brake, wheel weights, and road wear and resuspension of dust from the road surface) in near-road or ambient air, with the aim of disentangling the contributions of fresh and re-entrained non-tailpipe emissions from each other and from tailpipe emissions in future air quality exposure and health assessment studies.
    a. Develop methods to characterize the size distribution (e.g., ultrafine vs. larger particles), morphology, and composition of real-world non-tailpipe particulate emissions and how they vary in space and time, for example as a function of distance from roads, traffic composition and volume, and/or environmental conditions.
    b. Develop approaches to differentiate non-tailpipe emissions from specific processes (e.g., brake, tire, and road abrasion), vehicles of different sizes, weight, powertrain (i.e., combustion, hybrid, and electric; and conventional vs. regenerative braking), and driving conditions (e.g., highway driving vs. smooth flow at lower speeds or stop-and-go urban driving).

   c. Apply one or more appropriate methods (e.g., source apportionment) to quantify the contribution of fresh and re-entrained non-tailpipe PM emissions to near-road concentrations of PM relative to other sources, including tailpipe emissions.

2. Develop or extend existing approaches to measure or model total and/or process-specific (e.g., brake, tire, and road abrasion) non-tailpipe PM in the near-road environment that can be used for human exposure assessment.
3. Estimate current and future potential impacts of non-tailpipe emissions from passenger and/or commercial (including conventional braking light-duty, conventional heavy-duty, hybrid, and electric) vehicles on air quality, exposure, and/or estimate the potential contribution of non-tailpipe emissions to health burden attributable to ambient $PM_{2.5}$ mass. Such efforts should use realistic projections of regenerative braking technology efficiency and prevalence, friction material changes, low rolling resistance tires, and tire performance improvements.

Given budget constraints and practical considerations, HEI does not expect that any proposal will meet all these objectives but will aim to fund complementary studies that address the breadth and depth of the objectives. Addition of one or more of these objectives to ongoing health studies would be of interest, as long as the applicants provide sufficient information to show that the investigators conducting the ongoing health study are interested in the additional component and will commit to collaborate. In addition, applicants need to show that the proposed work submitted to the RFA can be clearly distinguished from the ongoing work funded by other institutions.

KEY STUDY DESIGN FEATURES

HEI considers the following features of the study design important to meet the overall objectives of this RFA.

Consideration of sources

Non-tailpipe sources

Applicants may focus on characterization of any or all sources of non-tailpipe PM, including tire, brake, and road wear and resuspension of dust from the road surface. Comparative analyses of multiple non-tailpipe components that treat each component in equal depth would be responsive, as would studies that address a single source of non-tailpipe PM in-depth.

Other sources

When considering potential tracers, applicants should consider other (i.e., tailpipe and non-vehicular) sources and describe the extent to which the tracer species are specific to non-tailpipe PM. The study design and analyses should differentiate among pollutant sources to the maximum extent possible. Inclusion of other spatially correlated variables that could help to differentiate between multiple sources is encouraged.

Pollutants

Applicants should focus on pollutants or combinations of pollutants that are related to non-tailpipe PM emissions (e.g., specific metal [Fe, Zn] or organic components), with justification for why the selected components are applicable for the source. Proposals may focus on chemical components (e.g., Cu) that are currently being reduced in new brake-pad formulations, but if so, applicants must explain how the study will be informative for assessing current and future impacts. Studies that incorporate multiple pollutants are preferred.

Inclusion of $PM_{2.5}$ mass is required because this pollutant is typically regulated. However, studies that primarily consider $PM_{2.5}$ mass without PM components or such physical properties as particle size distribution and morphology will not be considered responsive. Measurement of traditional tailpipe exhaust pollutants (e.g., NO_2, elemental carbon, or black carbon) at the same spatial and temporal resolution and levels of accuracy and precision as the non-tailpipe measurements is also desirable to aid in disentangling non-tailpipe emissions from tail-pipe emissions and other environmental sources and to eventually assess co-pollutant exposures or effects of pollutant mixtures.

Geographic location

Studies in North America, Europe, and other areas where air pollution sources, mixtures, and ambient concentrations are comparable to those in North America will be considered responsive. Both previously studied areas and areas where extensive space-time characterization of air pollution has not been performed (e.g., smaller urban, suburban, and rural areas) are of interest. The geographic parameters of the study should be chosen with consideration of the expected measurable spatial distribution of PM from non-tailpipe emissions.

Relevance for health effects of current fleet

Proposed studies should focus on impacts of current on-road vehicle fleets in areas near major roads with different traffic and driving conditions. Proposals based on archived samples will not be considered responsive unless evidence is provided that the archival samples were collected under fleet composition and traffic conditions that reflect current circumstances. Although no health component is required in the proposals for this RFA, applicants should describe how the study results will inform future study of health effects of non-tailpipe PM emissions.

Ease of application in later studies

Preference will be given to studies that use methods and techniques that are readily available (i.e., without the need for specialized equipment) and that can be adopted in support of epidemiological studies that require large numbers of samples. The RFA is meant to support applications and assessment of potential existing methods and not to support early development of new technologies.

Statistical analysis

A strong statistical analytic plan demonstrating the ability of the proposed study to answer the research questions will be required.

RESEARCH TEAM

The research team should possess the full range of expertise to conduct the proposed research. The Principal Investigator (PI) must demonstrate a record of producing high-quality and objective research in areas relevant to the proposed work and be affiliated with an established research organization. The full team can include the PI, their immediate team (other faculty, research scientists, post docs, students, and technicians), co-investigators or collaborator(s) at the same or other institutions, and consultants. The team should include members who have expertise needed to implement the proposed research, for example, emissions measurement and analysis, exposure assessment, statistics, environmental monitoring and modeling methods, brake or tire design, and road surface engineering. Applicants are also encouraged to engage with epidemiologists, biostatisticians, and other health experts to inform study design and to interpret findings. Preference will be given to proposals that show evidence for consideration on how the data from the proposed project might be used for future health studies.

HEI strongly encourages applicants to diversify their research teams by including individuals from groups that are underrepresented in environmental assessment and health research and, to the extent appropriate for the study location(s), attuned to and knowledgeable about the communities in which the studies will take place. For this purpose, HEI has adopted the National Institutes of Health (NIH) definition of underrepresented populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise.[1] The team's technical proposal ideally will be informed by engagement with experts who represent multiple sectors (e.g., academia, communities, regulatory and public health agencies, industry, and

[1] NIH's definition of underrepresented populations includes individuals from racial and ethnic groups underrepresented in health-related sciences on a national basis, individuals with disabilities who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, and individuals from disadvantaged backgrounds, recognizing that women from these three backgrounds face particular challenges at the graduate level and beyond in scientific fields (Source: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

non-governmental organizations) and will include them in research, as appropriate.

The proposal must clearly identify each team member, their affiliation, and role in the research. The team should have access to study sites (as evidenced by letters of support in the proposal, if applicable) and have or obtain access to facilities, equipment, and instrumentation needed to support the proposed research. If investigators plan to use data or materials (e.g., filter samples) from previous research, information on the type of data available (including the period, location, and frequency of when the measurements were taken) and quality assurance should be included. The application should include a letter from the investigator who owns the data or the materials that states willingness to share the data with the applicant and with HEI, if requested (see the "Provision of Access to Data Underlying Funded Studies" under the HEI Policy on Data Management, Preservation and Access).

POLICY ON DATA ACCESS

Providing access to data is an important element in ensuring scientific credibility and is particularly valuable when studies are of regulatory interest. HEI has a long-standing policy to provide access to data for studies that it has funded in a manner that facilitates the review and validation of the work. The policy also protects the confidentiality of any subjects who participated in the study and respects the intellectual interests of the investigators who conducted the study. Please refer to www.healtheffects.org/accountability/data-access-transparency for the HEI Policy on the Provision of Access to Data Underlying HEI-Funded Studies.

HEI intends for any measurements, model predictions, statistical code, and new approaches generated under this RFA to be made publicly available. Applicants will be expected to include a plan for data sharing in a publicly accessible forum to be linked on HEI's databases webpage at submission or publication of the final report. Where data are provided by a third party, a process for other investigators to obtain and work with the data should be described.

A study funded under this RFA might generate samples that have value for future analysis after the completion of the study. If this situation occurs, HEI might work with the funded investigators to store the samples or have additional analyses done using a different method.

BUDGET AND TIMELINE

The funding cap for each study will be $800,000 (total budget) for studies of 2 to 3 years in duration. Preparation of the final report should be included in the budget and timeline of the final year of the study. A total of up to $2.5 million will be available for this program. HEI expects to fund up to 3 studies from this RFA.

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The submission and review of applications for RFA 21-1 will entail a two-stage process.

1. Investigators should submit a **Preliminary Application by January 19, 2022**. The HEI Research Committee will discuss the preliminary applications and invite several investigators to submit a full application.
2. Invited investigators should submit a **Full Application by May 25, 2022**. Full applications will be reviewed by a Special Review Panel before consideration by the Research Committee.

PRELIMINARY APPLICATION

PROJECT PLAN

The 4-page preliminary application should contain a brief description of the project plan, including proposed specific aims, study design and methods, exposure and outcome data to be accessed or collected, sources of data and data collection methods, and data analysis plans. Sources, types, and description of all data to be collected or used in the study should be included. If the proposed study will be conducted in stages or will include multiple inter-related sub-studies, the preliminary application should present plans for each sub-study separately and describe how anticipated results will be integrated. The application should also include a discussion of the overall goal of the study and how anticipated results will contribute to the objectives of the RFA.

The preliminary application should describe how the proposed study will develop, evaluate, and apply real-world exposure indicators of non-tailpipe PM emissions from motor vehicles and to assess the impacts of such emissions on air quality, human exposure, and human health, as outlined in this RFA. Key issues include how to identify and validate exposure indicators to disentangle non-tailpipe and other sources; develop or extend existing human exposure assessment approaches to non-tailpipe PM; and estimate current and future impacts on air quality, exposure and/or potential contribution to health burden attributable to ambient $PM_{2.5}$ mass.

EXPERTISE AND BUDGET

The application should include specific fields of expertise among anticipated collaborators and a brief description of how their expertise would contribute to designing and conducting the study, analyzing the data, and interpreting study findings. When indicated, a list of special equipment and facilities that would be available for the project should be included. The application should also include an estimate of the time and an approximate estimate of funds required to complete the study. Detailed budget pages are not required at this time.

The preliminary application should not exceed 4 pages (excluding references) using the form provided. Please note that the required font size is **11 point with 1-inch margins**. Brief (2-page) curricula vitae of the Principal Investigator (PI) and each co-investigator should be submitted with the application. Investigators will be informed whether or not to submit a full application after the Research Committee has considered the preliminary application.

SUBMISSION AND DEADLINE

Preliminary applications should be submitted electronically by **January 19, 2022**, and will be discussed at the meeting of the Research Committee in February or March 2022. Questions regarding applications should be directed to Dr. Allison Patton at +1-617-488-2306 or *apatton@healtheffects.org*.

Please send the preliminary application by email to

Ms. Lissa McBurney
Senior Science Administrator
Health Effects Institute
75 Federal Street, Suite 1400
Boston, MA 02110, USA
Tel: +1-617-488-2345
Fax: +1-617-488-2335
funding@healtheffects.org

FULL APPLICATION

Invited full applications should provide in-depth information on aspects presented in the preliminary application: the study aims, design, rationale, methods, and statistical analyses, and how findings would contribute to the field. The full application should also describe in detail how the proposed study will develop, evaluate, and apply real-world exposure indicators of non-tailpipe PM emissions from motor vehicles and to assess the impacts of such emissions on air quality, human exposure, and human health (see above) and include a brief review of the published literature that is pertinent to designing and conducting the study and interpreting its findings.

If data from other studies are going to be used, information on the type of data available (including the period, location, and frequency of when the measurements were taken) and quality assurance should be included. Applicants should also discuss whether they will need to obtain IRB approval. Where applicable, a letter from the investigator who owns the data should be submitted and state their willingness to share the data with the applicant and with HEI, if requested (see HEI Policy on the Provision of Access to Data Underlying HEI-funded Studies). In addition, the full application should include a plan for data sharing and accessibility at the end of the study.

Investigators invited to submit a full application should use **forms F-1 to F-12** and consult the Instructions for Completing the Application. Application forms can be downloaded from *www.healtheffects.org/funding*. Please note that the required font size is 11 point with 1-inch margins. Form F-12 is separated from the rest of the application upon receipt. The data are kept confidentially and not considered for funding decisions; HEI strongly appreciates completion of this form to track diversity of applications and funded investigators in an effort to continue to invest in, and expand HEI's investment into DEI efforts as part of its 2020 commitment https://www.healtheffects.org/announcements/taking-steps-toward-action-inclusiveness. The application forms should be turned into a PDF with appropriate bookmarks before submitting.

SUBMISSION AND DEADLINE

Invited full applications should be submitted to Ms. Lissa McBurney at HEI at the address above. Full applications for RFA 21-1 must reach the offices of the Health Effects Institute by **May 25, 2022.** HEI will acknowledge receipt of the application. Applications will be reviewed by an external review panel (see below) and discussed by the Research Committee in July 2022.

Full applications will be evaluated in a two-stage process: an external review followed by an internal review.

EXTERNAL REVIEW

Applications undergo a competitive evaluation of their scientific merit by an ad hoc panel of scientists selected for their expertise in relevant areas. Applications may also be sent to external scientists for additional evaluation. The panel will evaluate applications according to the following criteria:

- Relevance of the proposed research to the objectives of the RFA
- Scientific merit of the hypothesis to be tested, the study design, exposures and outcomes to be evaluated, accessibility to existing databases of ambient air, meteorological monitoring, registries, health care utilization or other resources as appropriate, proposed methods of data collection, validation, and analysis, including adjustment for potential confounding factors, such as smoking, and development of innovative analytic methods of data analysis
- Personnel and facilities, including
    - Experience and competence of the PI, scientific staff, and collaborating investigators
    - Extent of collaboration among investigators in pertinent fields who will contribute to the conduct of the study
    - Adequacy of effort on the project by scientific and technical staff
    - Adequacy and validity of existing data and data to be collected
    - Adequacy of facilities
- Reasonableness of the proposed cost

The applications ranked highly by the review panel may be additionally reviewed by a statistician regarding the experimental design and analytical methods.

INTERNAL REVIEW

The internal review is conducted by the HEI Research Committee and generally focuses on the applications ranked highly by the external review panel. The review is intended to ensure that studies funded constitute a coherent program and address the objectives of the Institute. The Research Committee makes recommendations regarding funding of studies to the Institute's Board of Directors, which makes the final decision.

CONFLICTS OF INTEREST

HEI's procedures for conflicts of interest are similar to the guidelines set forth by NIH. Members of HEI's sponsor community are excluded from participating in RFA development, applying for support, application review, and funding decisions.

HEI invites external reviewers (or in the case of a major RFA, Review Panel members) who are unlikely to have a conflict of interest with the proposal(s) they are asked to review. A conflict occurs when the reviewer is named on the application in a major professional role; the reviewer (or close family member) would receive a direct financial benefit if the application is funded; the PI or others on the application with a major role are from the reviewer's institution or institutional component (e.g., department); during the past three years the reviewer has been a collaborator or has had other professional relationships (e.g., served as a mentor) with any person on the application who has a major role; the application includes a letter of support or reference letter from the reviewer; or the reviewer is identified as having an advisory role for the project under review. In addition, HEI Staff screen external reviewers for potential conflicts of interest with other applicants who have submitted a proposal under the same RFA.

For Review Panel members and Research Committee members, in some situations it may not be possible to avoid all possible conflicts of interest as outlined above. In such cases, Review Panel and Research Committee members who have a conflict of interest will not be assigned to review the application(s) in question and will be asked to leave the room during the discussion of those application(s). They will also not score or vote on the application(s) at issue and refrain from commenting on them during the overall discussion, and in the case of the Research Committee, from all deliberations regarding recommendation of applications for funding. If several Research Committee members are recused from the overall discussion of applications for such reasons, HEI will invite external consultants to join the Committee to fill in the missing expertise.

This peer review system relies on the professionalism of each reviewer, Review Panel member, and Research Committee member to declare to HEI the existence of any real or apparent conflict of interest. If a reviewer feels unable to provide objective advice for any other reason, they are expected to recuse themself from the review of the application(s) at issue.

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