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A Health Effects Institute Affiliate

Request for Applications (RFA E20-1 and RFA E20-2):

Community Exposures Associated with Unconventional Oil and Natural Gas Development

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INTRODUCTION

The Health Effects Institute-Energy (HEI-Energy) seeks to fund research to improve characterization of potential human exposures originating directly from the onshore development of oil and natural gas from shale and other unconventional, or low permeability, resources in the United States (UOGD). UOGD refers to the development and production of oil and natural gas as practiced starting around the beginning of the 21st century through multistage hydraulic fracturing in horizontal wells. UOGD processes occur on and off the well pad and include:

- *field development*: exploration, site preparation, vertical and horizontal drilling, well completion (casing and cementing, perforating, acidizing, hydraulic fracturing, flowback, and well testing) in preparation for production, and management[1] of wastes;
- *production operations*: extraction, gathering, processing, and field compression of gas; extraction and processing of oil and natural gas condensates; management of produced water[2] and wastes; and construction and operation of field production facilities; and
- *post-production*: well closure and land reclamation.

In 2019, HEI-Energy released two companion reports - a draft survey of the literature relevant to environmental exposures associated with UOGD (HEI-Energy Research Committee 2019a) and a systematic review of the epidemiology literature on the health effects associated with UOGD (HEI-Energy Research Committee 2019b). These reviews summarize what is known about potential human exposures and health effects associated with UOGD. The survey of exposure literature provides essential supporting information for this RFA (Attachment 1).

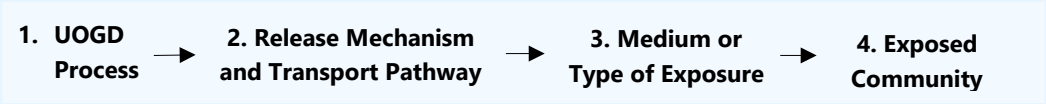
Current evidence indicates that people can be exposed to chemical agents (e.g., criteria and hazardous air pollutants, radioactive material, indicators of produced water, and odorous compounds) and non-chemical agents (e.g., noise, light, and vibration) released from UOGD processes, but there are important gaps in knowledge about these exposures that must be addressed to better understand potential impacts on health. Research conducted in response to this solicitation is expected to address the most important knowledge gaps about UOGD-related exposures. The overarching goal of the Energy Research Program is to identify the spatial and temporal range of potential human exposures arising from UOGD processes across the United States, and the conditions under which they occur. The anticipated results will be crucial to improving understanding of, and future research on, the health impacts of UOGD.

This solicitation includes two Requests for Applications (RFAs) for research that quantifies the temporal and spatial variability in UOGD exposures associated with air quality impacts and noise (E20-1) and UOGD exposures associated with water quality impacts (E20-2). An ideal exposure study will determine whether a complete exposure pathway connects an environmental release from a UOGD process with exposure in a community (Figure 1), while simultaneously distinguishing UOGD-related exposures from other sources (e.g., conventional oil and gas development, other industrial activities, and non-UOGD traffic, as well as naturally occuring chemicals). Communities can include those in close proximity to UOGD and those farther away that are affected by regional changes in environmental quality.

[1] Management of wastes and produced water refers to their handling from creation to disposal, including collection, storage, transport, treatment, reuse, recycling, and disposal.

[2] Produced water is naturally-occurring water that comes out of the ground along with oil and gas. (Adapted from: American Geosciences Institute 2019). The characteristics of produced water vary and use of the term often implies an inexact or unknown composition. (Adapted from: Schlumberger 2019)

Figure 1. Conceptual model of a complete exposure pathway associated with UOGD. Adapted from the U.S. EPA's "Guidelines for Human Exposure Assessment" (U. S. Environmental Protection Agency 2016a).



Documentation of a complete exposure pathway associated with UOGD (Figure 1) consists of the following elements:

1. Identification of the UOGD process (e.g., phase of development, mitigation technique, transportation of materials, and management of waste) that is a source of a chemical or noise, while accounting for evolving industry operational trends;
2. Characterization of the mechanisms (e.g., authorized or accidental releases, short-term and long-term processes) that give rise to an agent's release to the environment and transport pathways (e.g., volatilization, deposition, or leaching) that dictate how it migrates among environmental media (e.g., air, water, and soil) or is transformed (e.g. secondary pollutant formation) within these media;
3. Assessment of the levels of the agent in an environmental medium to which people might be exposed and the route(s) of exposure (i.e., inhalation, ingestion, or dermal contact) for the agent; and
4. Characterization of the magnitude, frequency, and duration of exposure for a specific community.

Documentation of a complete exposure pathway provides critical information necessary to assess its importance for health and for informing possible decision-making related to exposure reduction.

Background and Rationale

Increased Rate and Intensity of Oil and Natural Gas Development in the United States

The scale and rate of onshore oil and natural gas development since the early 2000s differ markedly from earlier development, stemming from technologic changes involving increased use of hydraulic fracturing combined with horizontal drilling. While hydraulic fracturing has captured much public attention, this process alone is not new. Neither is horizontal drilling or the extraction of oil and gas from unconventional formations, such as tight (i.e., low permeability) sandstone and shale. What is new is the use of high-volume (millions of gallons of water per well) multistage hydraulic fracturing combined with horizontal drilling (thousands of feet in length).

This combination of technological innovations has influenced the scale of development and where development is feasible. With their extensive number of fracture stages along lengthy horizontal wells, today's unconventional oil and gas wells intersect more of the targeted oil- or gas-bearing rock than earlier vertical wells, which involves the following:

- Larger well pads with extensive amounts of equipment that are transported to and from the pad;
- More raw materials that must be transported to the well pad for drilling, cementing and hydraulically fracturing the target hydrocarbon-bearing formation to produce the oil or gas;
- More liquid and solid waste from multiple wells drilled on one well pad that must be captured, transported, and treated, for reuse or ultimate disposal;
- A longer period of industrial activity required at a single well pad when multiple wells are developed on it; and

- Increased truck traffic, changing demands on community infrastructure, and other possible community effects associated with population mobility.

Consequently, UOGD can be associated with a wide range of potential exposures to chemical and non-chemical agents, and the rapid expansion of this development has given rise to concerns about potential effects on human health.

Overview of Potential Human Exposures to UOGD and Important Knowledge Gaps

This section briefly summarizes what the two reviews released by HEI-Energy (HEI-Energy Research Committee 2019a, 2019b) revealed about the potentially complete UOGD exposure pathways (Figure 1) and important gaps in knowledge that remain.

1. UOGD Processes. UOGD processes give rise to chemical and non-chemical releases to environmental media that are complex and highly variable in terms of both amount and composition. Such releases are a function of numerous process-related factors, including the characteristics of the oil and natural gas resources, variation in operator practices, and regulatory requirements. In addition, the level of UOGD activity can vary widely across regions and over time in response to fluctuating market conditions.

   UOGD processes associated with different phases of UOGD development (i.e., pad preparation, drilling, completion, flowback, production, associated vehicle traffic, and waste management) can influence the type, timing, and quantity of chemical and non-chemical agents released from UOGD that may ultimately result in human exposures. Exposures might additionally be related to the oil and natural gas itself, chemicals used to drill and develop the well, chemicals in produced water, vehicle exhaust, and emissions from various types of equipment (e.g., compressors and pneumatic devices). Operator practices can influence the potential releases to the environment (e.g., using a protective liner on a well pad or a quiet frac fleet[3]), and an operator's ability to monitor and respond to releases when they occur. These operational factors — combined with local terrain and hydrogeological and meteorological conditions — affect the composition, magnitude, frequency, and duration of potential human exposures.

2. Release mechanisms and transport pathways. UOGD emissions to air can occur on or off well pads, originating from equipment and other point and mobile sources or resulting from fugitive releases (e.g., leaks from storage tanks or volatilization from surface spills). After release into the environment, chemicals are dispersed and can react in the atmosphere or in the surface or subsurface environments, leading to widely varying concentrations and potential exposures at local and regional scales (Allen 2014; Bell et al. 2017; Mitchell et al. 2015; Vaughn et al. 2018; Zavala-Araiza et al. 2015).

   In air, understanding the complexities of atmospheric transport and chemistry of UOGD emissions is key to quantifying air-related exposures. UOGD studies conducted to date have included measurements of air quality, modeling of air quality, and combinations of measurement and modeling approaches. A few studies have leveraged air quality monitoring data or modeling to address regulatory needs, such as assessing setback distances and distance decay gradients between UOGD and residences (Banan and Gernand 2018; Garcia-Gonzales et al. 2019; Haley et al. 2016; McCawley

[3] See, for example, "Energy Pipeline: Quiet Fleet set to cut the noise at drilling sites in DJ Basin," *Greeley Tribune*, February 16, 2017; Accessed at: https://www.greeleytribune.com/news/energy-pipeline-quiet-fleet-set-to-cut-the-noise-at-drilling-sites-in-dj-basin/.

2013). Still others attempted to identify the factors that gave rise to the subset of UOGD processes with the highest emissions, which are sometimes called "super-emitters" (e.g., Zavala-Araiza et al. 2017). To identify stochastic events and high emission processes, studies have required collection of data at high temporal and spatial resolutions. Despite this body of work, studies have largely been specific to the set of conditions under investigation. There is a lack of studies focused on evaluating mechanisms of release and transport that can facilitate application of results to other sets of conditions.

UOGD releases to surface water and groundwater can result from authorized or accidental releases to the environment. Examples of authorized releases include permitted discharge of treated UOGD wastewater effluent to surface water or use of produced water that meets required quality criteria for applications outside the oil and gas production site (e.g., irrigation of crops, watering of cattle, and de-dusting or de-icing roads). Opportunities to reuse produced water are being reviewed by U.S. EPA (U.S. Environmental Protection Agency 2019) and some states (Goodman 2017; Lyons et al. 2019; State of New Mexico and U. S. Environmental Protection Agency 2018), and research is underway to understand how produced water can be managed in a way that protects public health and the environment (e.g., Consortium formed by New Mexico State University and New Mexico Environment Department).

While protections have been put in place to prevent accidental chemical releases to groundwater and surface water, releases can occur due to causes such as a wellbore failure, malfunctioning equipment, or other accidental conditions (Maloney et al. 2017). The mobility of a particular chemical and its fate in the environment depends on its chemical and physical characteristics and the characteristics of the receiving surface water body or subsurface aquifer.

Release of non-chemical agents, such as noise, vibration, and light, also occur during routine operations or through unintended mechanisms.

3. Media or type of exposure. A sizable literature on ambient air quality, including measurement and modeling studies, and a growing literature on noise levels near UOGD are now available. Some of the air quality literature provides reviews of large quantities of state-collected data in oil and natural gas-producing states, such as Colorado, Pennsylvania, and Texas. While many of these studies provide valuable information for understanding human exposures, only a small group of studies have been conducted with the direct aim of estimating potential human exposures to UOGD (e.g., Allshouse et al. 2019; Maskrey et al. 2016; Paulik et al. 2018; Pennsylvania Department of Environmental Protection 2018; Steinzor et al. 2013). Additionally, questions remain about whether the existing studies and databases represent the full range of processes that may lead to exposure across multiple time scales and regions.

   A review by the U.S. EPA (2016b) did not identify extensive contamination of water related to UOGD but cited instances where contamination has occurred and knowledge gaps that remain. Research on changes in surface water or groundwater quality from accidental UOGD releases is challenging given the practical limits on knowing when and where such releases might occur. Once a release to surface water is known to have occurred, researchers may be able to detect associated impacts (Cozzarelli et al. 2017). Accidental releases to the subsurface pose a much greater challenge than releases to surface water. They typically require substantial effort and resources to determine the extent and severity of impacts on groundwater quality and the conditions that influence mobility of the release in the subsurface environment.

   A major challenge in quantifying exposure to UOGD is distinguishing UOGD-related exposures from other sources of the same chemical and non-chemical agents in environmental media. Examples

include conventional oil and natural gas development, other industrial sources, vehicle exhaust from traffic unrelated to UOGD processes, and natural sources. Many air and water studies have not endeavored to attribute measured or modeled agent concentrations to a specific UOGD process. Instead, investigators have measured or modeled concentrations in air and water, or noise levels, and compared measured levels among locations at varying distances from UOGD processes, time periods, or different equipment and mitigation methods (e.g., use of sound barriers).

A subset of air and water quality studies has used isotopic tracers and other markers associated with UOGD in an effort to isolate its effects from that of other sources. Some air quality studies have incorporated chemical transport modeling to quantitatively link chemical concentrations in air with specific UOGD sources (e.g., flaring and compressor station emissions) and to distinguish UOGD from other sources. Other studies have measured chemicals in air at various distances from UOGD sources and used source apportionment modeling or other statistical techniques to disentangle UOGD processes from other sources (Bari and Kindzierski 2018; Goetz et al. 2015; Nathan and Lary 2019; Schade and Roest 2016; Swarthout et al. 2015; Zielinska et al. 2014).

4. Exposed communities. People living in communities affected by UOGD may be exposed to a variety of chemical and non-chemical agents. However, studies to date have rarely endeavored to document community exposures through a complete exposure pathway, in which investigators take measurements that reflect the locations and scenarios under which community members might be exposed and connect those measurements to UOGD processes using modeling techniques, detailed process data, or chemical tracers. Consequently, we do not have a cohesive understanding of how – and the extent to which – processes, regulations, and regional conditions (e.g., gas versus oil deposits) may lead to exposure via the air and water pathways in human populations, and whether those exposures have implications for human health.

   In addition to data on levels of chemical and non-chemical agents in various media, exposure assessment includes information on time-activity patterns, magnitude, frequency, and duration of a potential exposure, and the likelihood of exposure occurring. With the exception of human health risk assessments, existing literature related to UOGD does not quantify potential exposures to specific populations and contains limited information about the frequency and duration of exposure. The location and general characteristics of potentially exposed community(ies) need to be identified to understand whether an exposure might occur and, if so, to interpret its importance.

Summary. The quantity of data on levels of UOGD-related agents in the environment continues to increase along with efforts to use the data to quantify human exposure. Despite the amount of work conducted to date, important gaps remain in our understanding of who might be exposed, the full range of exposures, which processes lead to exposures, and how exposures vary over time and across regions. Specifically, few studies to date provide the information necessary for linking chemical or non-chemical agents from UOGD processes with exposed communities. In addition, the applicability of study results to UOGD operations, geographic areas, and populations beyond those investigated in the studies is not clear. Given the current state of knowledge, HEI-Energy has reached the conclusion that further investigation is needed to improve understanding of human exposures to UOGD, with research designed to support decision making about how to protect human health by community members, public health officials, regulators, oil and gas operators, and others.

Research Priorities to Address Knowledge Gaps

Stakeholder Input. To define priority research areas for this solicitation, the HEI-Energy Research Committee ("the Committee") considered findings from its reviews of the literature (HEI-Energy Research Committee 2019a, 2019b) along with recommendations received from a wide range of

stakeholders. At research planning workshops in Boston, Denver, and Austin, the Committee heard the research priorities of regulators, public health officials, community groups, environmental health nongovernmental organizations, industry, and research scientists actively engaged in UOGD-related exposure and health research. The priorities are summarized in three workshop reports[4] and represent the views of individual workshop participants.

The most common recommendations focused on the need to capture heterogeneity in potential exposures across UOGD operations, regions, and populations, distinguish potential UOGD exposures from other sources, and provide information that is actionable and involves partnerships from multiple sectors. Workshop participants from all sectors sought research that provides a scientific basis for understanding how close is too close for UOGD near residential neighborhoods, schools, and other sensitive land uses. Suggestions for research designed to investigate exposure to chemicals in air dominated the discussion, but workshop participants also suggested the need for research on exposure to noise from UOGD processes and expressed concern and noted the lack of data about potential surface water and groundwater quality impacts from UOGD processes, including management of wastewater.

Research Priorities. Overall, the Committee noted through its review of the exposure literature and consultation with stakeholders that few studies focused specifically on human exposure to UOGD and understanding how it might vary with different operations, locations, and populations. The Committee additionally noted the need for detailed exposure assessment measures in its review of the epidemiology literature (HEI-Energy Research Committee 2019b).

As a first step in addressing knowledge gaps about human exposures from UOGD, the two RFAs presented here focus on exposures related to UOGD impacts on air quality, water quality, and noise levels. Based on input received during stakeholder workshops and the scientific literature, the Committee has recommended apportioning 80% of available funds to research on exposures arising from air quality impacts of UOGD, with a supplemental line of investigation about exposure to UOGD-generated noise. UOGD emissions occur during routine operations throughout major oil and natural gas-producing regions. While the air quality literature provides an extensive amount of data, it is not clear how well the data encompass the full variability in exposures regions and UOGD operational conditions or provide a direct link between UOGD processes and community exposures (Figure 1). Exposures to UOGD-generated noise also occur under routine operations, but the literature investigating community exposures to noise is underdeveloped. For these reasons and because air quality and noise exposures are invariably occurring to some degree, the Committee concluded that such exposures merited greater investment in research than exposures through other environmental media.

Based on input received during stakeholder workshops and the scientific literature, the Committee has recommended apportioning 20% of available funds to research on exposures arising from water quality impacts of UOGD. These operations can result in surface water and groundwater quality impacts, and much public attention has been focused on the concern about exposure to drinking water contaminated by UOGD. Except for permitted discharges and uses of UOGD produced water, routine operations are designed to prevent releases to groundwater or surface water. Therefore, such releases occur only under

[4] The three reports are available at HEI-Energy's website:
- January 2018 Scoping Meeting, Boston, MA, available at: https://hei-energy.org/sites/default/files/4.hei_energyresearchprogram_scopingmeetingsummary_final.pdf
- July 2018 Workshop, Denver, CO, available at: https://hei-energy.org/sites/default/files/hei_energy_jul_2018_workshop_report.pdf
- September 2018 Workshop, Austin, TX, available at: https://hei-energy.org/sites/default/files/hei_energy_-sep_2018_workshop_report_final.pdf.

accidental conditions, making them especially challenging to study, although many have tried, for example, through review of spill records or investigation of specific spill incidents (Maloney et al. 2017). Permitted releases of UOGD produced water or treated wastewater to surface water are not ubiquitous at this time, and so opportunities to conduct research are also rare. For this reason, literature to date predominately includes studies that attempted to measure and model UOGD impacts on both surface and groundwater quality that have or might have arisen from accidental conditions. At this time, questions remain about the potential for surface and groundwater contamination through routine and accidental conditions.

UOGD could contaminate other media, such as crop uptake of contaminated groundwater or sediment contamination resulting from spills into surface water. However, the Committee has chosen to focus primarily on air-related exposures given their prevalence and, consequently, the opportunity to provide widely useful research. Water-related exposures also merit research attention given knowledge gaps in the literature combined with the need to answer ongoing questions about the possible importance of these exposures for health.

To best inform decision-making, HEI-Energy seeks high-quality and impartial research that allows for the detection of complete exposure pathways between one or more aspects of UOGD processes and community exposures.

Overall Objectives

Investigators must design studies that are able to document one or more complete exposure pathway(s), should one exist, between UOGD process(es) and a community(ies) potentially exposed to one or more specific UOGD agent(s). Research should inform future health studies and be designed in an efficient way to achieve the greatest possible understanding of the variation in potential human exposures from routine operating conditions but also with the ability to document those associated with accidental conditions. Successful proposals will satisfy the evaluation criteria listed below under "Evaluation Process for Full Applications."

Air Quality and Noise (RFA E20-1)

For the investigation of exposures related to air quality, HEI-Energy seeks to fund studies that apply a combination of approaches to quantify the spatial and temporal variability in human exposures to UOGD-generated atmospheric chemical concentrations. Such air quality investigations also provide an opportunity to monitor noise levels associated with UOGD processes. The research should maximize applicability, or generalizability, of the findings to locations, operations, and communities beyond the study areas. To advance this objective, HEI-Energy anticipates funding research that couples established, rigorous methods to measure air and noise exposure at multiple spatial scales with equally rigorous fate and transport modeling. The modeling should incorporate study measurements and provide a theoretical framework for interpreting study findings and using them to predict exposures under different conditions, such as other UOGD processes or environmental conditions, and that allow for scalability.

Investigators might incorporate novel approaches to quantifying exposure and compare results to more traditional exposure assessment approaches as a component of their study. Such studies should include a quantitative evaluation of the added value of the novel approach (e.g., reduced measurement error).

Water Quality (RFA E20-2)

The potential effects of UOGD on water quality have received much attention in the scientific literature, much of which is summarized in U.S. EPA's review of hydraulic fracturing impacts on drinking water (U.S. Environmental Protection Agency 2016b). These studies highlight the challenge of studying the

scale and types of water-related exposures that result from accidental conditions (e.g., spills and leaks), especially those that involve subsurface contamination. Nevertheless, these exposures can occur with accidental or intentional releases. Water quality effects can become evident soon after release of UOGD agents to the environment, or they might go undetected for years. HEI-Energy seeks synthesis and modeling of existing data and original research to better understand the nature, extent, and frequency of potential exposures related to UOGD impacts on water quality.

Specific Objectives

Air Quality and Noise (RFA E20-1)

E20-1 solicits studies in multiple oil and natural gas-producing regions in the United States to assess community exposures to chemicals in outdoor air and noise originating from UOGD. While this solicitation seeks studies in multiple U.S. regions, individual studies may focus on one or more regions.

Proposals should strive to meet all of the following specific objectives:

- Identify the UOGD processes that have resulted or might result in releases of chemicals or noise to outdoor air, and the potential for human exposure resulting from such releases.
- Quantify the magnitude, frequency, and duration of potential exposures to chemicals in outdoor air and to noise released from specific UOGD processes at multiple spatial and temporal scales.
- Quantify the influence of various factors (e.g., varying meteorology, topography, operational characteristics, proximity to populations, and population behavior) on potential UOGD-related human exposures to characterize variability in exposures and enable the results of the research to be generalized to other conditions.
- Estimate community exposures from UOGD sources across spatial and temporal scales relevant to a current or future assessment of potential health effects.
- Distinguish potential UOGD exposures from other conventional oil and gas development and any other background source, to the extent practicable.

In designing their studies, investigators are encouraged to implement a combination of monitoring and modeling techniques, incorporating existing data of high quality as appropriate. In deciding on sampling methods (e.g., mobile monitoring, in situ measurements, stationary monitoring, remote sensing, passive sampling, active sampling), investigators should weigh the relative utility of each with respect to accuracy, spatial coverage, temporal and spatial resolution, as well as personnel and analytical costs.

The choice of modeling approach should be based on the investigator's understanding and experience in developing atmospheric models, assessing their accuracy, and applying them to apportion sources of potential exposures (e.g., specific UOGD processes and other sources, such as conventional oil and natural gas development) under various operational and environmental conditions. Proposed models used for dispersion or source apportionment should have been previously evaluated for accuracy.

Water Quality (RFA E20-2)

E20-2 solicits studies to assess community exposures to chemicals in groundwater or surface water originating from UOGD.

Proposals should strive to meet all of the following specific objectives listed below:

- Determine the UOGD processes that have resulted or might result in releases to groundwater or surface water, and potential for leading to human exposure.

- Quantify the magnitude, frequency, and duration of potential exposures to chemicals in surface water or groundwater released from specific UOGD processes.
- Quantify the influence of various factors (e.g., varying geology) on potential human exposures to maximize the generalizability of the research and inform decision-making.
- Distinguish potential UOGD exposures from other conventional oil and gas development and any other background sources, to the extent practicable.

Analyses of Existing Data. HEI-Energy will fund synthesis and modeling of existing data related to potential UOGD impacts on water quality to address the specific objectives listed above. Successful efforts would augment rather than repeat previous work (e.g., Ground Water Protection Council 2019; Kiran et al. 2017; Maloney et al. 2017; U.S. Environmental Protection Agency 2016), with the overall goal of refining collective understanding of possible water-related exposures.

New Empirical Research. HEI-Energy will consider funding empirical research involving the collection of original data related to potential UOGD impacts on water quality that augment, rather than repeat, previous work. Such empirical research will be funded only for innovative ideas that address the specific objectives listed above that cannot otherwise be addressed through review of existing data.

Water quality research could build on recommendations of HEI's Special Committee on Unconventional Oil and Gas Development (2015). For the purpose of quantifying the impact of UOGD on short- and long-term trends in the quality of water resources, the Special Committee recommended the design of an optimal framework for determining baseline conditions and assessing impacts on water resources with the broadest possible geographic applicability:

> "The framework should be designed to ensure robust studies by specifying the spatial and temporal aspects of sampling needed to distinguish among conditions before, during, and after development; the types of samples that should be collected; the analytes and reporting limits that should be included; and the quality assurance protocols necessary to achieve the desired levels of precision and accuracy."

Such a framework would be supported by analysis of existing data or collection of new data to provide a strong foundation for future water quality research funded by HEI-Energy and others.

Key Features of a Study Design

UOGD Processes

HEI-Energy is interested in research designs that will facilitate enhanced understanding of the contributions of different UOGD processes to specific exposures. These include UOGD releases on well pads (e.g., chemical emissions to air from equipment and noise during drilling and completion) and from associated processes beyond the well pad, such as potential exposures related to transport of materials to and from the well pad (e.g., vehicle emissions and traffic noise), management of solid and liquid wastes, and emissions from processing plants and compressors in oil and natural gas production sites.

Routine and accidental conditions. HEI-Energy expects research to focus on exposures during routine UOGD operating conditions; however, any exposures associated with atypical operating conditions should be documented if they occur during the course of study.

UOGD operational trends. UOGD is subject to operational trends as a function of technological innovation, changing regulations, market conditions, and efforts to protect public health and the environment, trends which can be consequential for potential human exposures.

Air-related exposures can be influenced by a number of operational trends. Two examples involve leak detection and repair (e.g., Pacsi et al. 2019) and gas flaring (e.g., Dix et al. 2019). To the extent feasible, proposed research designs in response to RFA E20-1 should account for any such trends that are relevant to the proposed research.

A number of operational trends can also influence water-related exposures. One trend involves ongoing efforts to understand the feasibility of and possible impacts associated with recycling or reusing produced water within and beyond oil and gas production sites (e.g., Ground Water Protection Council 2019; State of New Mexico and U. S. Environmental Protection Agency 2018). Specific questions remain about the composition of produced water and the chemical and physical properties of its constituents that influence the potential for environmental mobility and human exposure. Research to answer these questions in the context of a complete human exposure pathway could enhance understanding of potential exposures from recycling or reusing produced water within and beyond production sites.

At this time, reuse and recycling of produced water from UOGD is occurring within oil and gas production sites and proposed research designs submitted in response to RFA E20-2 should account for any such trends that are relevant to the proposed research to the extent feasible. Reuse and recycling of produced water from UOGD outside of oil and gas production sites (e.g., road treatment and crop irrigation) is not prevalent nationally and, consequently, opportunities to collect data or analyze existing data are sparse; therefore, HEI-Energy does not plan to fund research specific to reuse or recycling of produced water outside oil and gas production sites under this RFA.

The trends noted here represent only a few examples that might need to be accounted for in proposed research.

Linking specific UOGD processes to exposed communities. There is strong interest in research that improves understanding about how variability in UOGD processes influences variability in UOGD exposures over time and space. Research should identify factors that drive this variability through collection of data with high temporal and spatial resolution. For example, research teams could coordinate with industry to collect detailed operational activity data to connect specific UOGD processes with exposures. Where feasible, investigators would collect baseline data followed by data collection over the UOGD life cycle, from well pad construction through production. To this end, a sampling location where UOGD is planned, but has not yet occurred, would be ideal to capture background sources.

Study Locations

HEI-Energy is seeking to fund air quality research in multiple major oil and natural gas-producing regions, given the differences in UOGD operational characteristics, airsheds, and geology across different parts of the United States. HEI-Energy will consider proposals from teams that will conduct research in one region or in multiple regions.

Investigators must provide a rationale for selected study locations and the extent to which they meet several criteria:

- Individually and collectively, the chosen locations should provide an opportunity to greatly increase understanding of variability in exposure as a function of variability in UOGD processes and meteorological, geological (e.g., oil versus gas resource), and other environmental characteristics,
- UOGD is occurring now and is expected to continue or expand in the future,
- UOGD is planned, providing an opportunity for investigators to partner with operators to define exposure conditions before and during UOGD operations,

- Proximity of potentially exposed communities,
- Ability to distinguish between UOGD and other possible sources of the chemical and non-chemical agents to be studied,
- Opportunity to assess exposures before and after the implementation of mitigation, and
- Opportunity for collaboration with communities, industry, and other decision-makers.

HEI-Energy recognizes that proposed study locations where collection of data relevant to assessing exposures has occurred or is already occurring provide an opportunity to capitalize on previous work. However, study locations without this advantage can still be useful in examining potential exposures and their variability. Moreover, given the rapidly-changing nature of the industry, HEI-Energy is most interested in research that captures exposures that reflect current and, if possible, emerging industry practices.

HEI-Energy is seeking to conduct water quality research that is focused on analyses of existing data and possibly new empirical research. Ideal research will be as broadly relevant as possible to varying conditions across oil and natural gas-producing regions of the United States.

Environmental Media

HEI-Energy is interested in improving the understanding of community exposures to UOGD chemical agents in the environment, primarily in outdoor air, surface water, and groundwater. As part of air quality studies, HEI-Energy is also interested in UOGD-generated noise.

Chemical and Non-Chemical Agents

HEI-Energy seeks research on chemicals agents in air or water that have implications for human health, including, but not limited to volatile organic compounds, notably benzene and other air toxics, criteria air pollutants, ultrafine particulate matter, radon and naturally occurring radioactive material (NORM) and technologically enhanced NORM[5], secondary pollutants of concern, and noise [A-weighted (dBA) and C-weighted (dBC)]. Additional chemical analytes might be selected if they can be used to facilitate source quantification (e.g., by using source apportionment techniques). Methane's contribution to greenhouse gas emissions is already the subject of major national research programs. Therefore, this topic is beyond the scope of this RFA, except where methane measurements might be useful for understanding other potential UOGD exposures. Investigators need not measure all of these agents or restrict their analysis to those listed above.

Investigators must provide a clear rationale for their selected agents of interest based on the following criteria:

- They have the potential to be consequential for human health, or
- They serve as markers (e.g., tracers or other indicators of contamination) of exposure.

[5] Technologically enhanced naturally occurring radioactive material (TENORM) is defined as "naturally occurring radioactive materials that have been concentrated or exposed to the accessible environment as a result of human activities such as manufacturing, mineral extraction, or water processing" (EPA. April 2008. Technologically Enhanced Naturally Occurring Radioactive Materials From Uranium Mining. EPA 402-R-8-005).

It is important to consider that, while many chemicals associated with UOGD have been identified, some remain proprietary (e.g., based on operator postings to the FracFocus database[6]) and other unknown chemical species might form from drilling or fracturing fluids under high temperature and pressure conditions in the subsurface environment (Allen 2014; Moore et al. 2014). The composition of flowback[7] and produced water is the subject of ongoing study. While HEI-Energy does not seek to fund studies with a singular focus on chemical identification, investigators may incorporate this research component into their overall proposed investigation if the basis for it is fully justified.

Data Collection Methods

Existing Data. In both air- and water-quality research, HEI-Energy seeks maximal use of existing data to support rigorous assessment of exposure across U.S. regions. Such data might include publicly available and privately owned sources of analytical chemistry data, UOGD operational data, chemical concentration data from existing air or water samples, and other data that is of sufficient quality and relevance to support the objectives of the proposed research. Additionally, the time period represented by the data should be relevant to understanding the impacts of current and possible future UOGD operating conditions. Proposed use of such data must be accompanied by a plan for ensuring its quality and for protecting confidentiality (see *Data Management, Preservation, and Access Policy*).

New Empirical Data. In air quality research, HEI-Energy seeks the development and application of methods to obtain direct measurements of UOGD-related agents on and near sites, downwind, at the regional level, as well as the investigation of how those levels vary in response to atmospheric conditions and topography. Use of continuous monitors, inexpensive sensors, passive (diffusive) samplers, and satellite-based observations may be of interest. Satellite data could potentially help to characterize historic exposures during both periods of heavy and light activity. The blending of inexpensive sensors, routine measurements, and remote observations could lead to a multiscale modeling framework to capture both near-field and regional exposures in a consistent fashion.

In both air and water-quality research, HEI-Energy expects investigators to use tested, rigorous methods but also welcomes ideas for innovative methods. Reporting quantitative measures of uncertainty (e.g., instrument measurement error) will be important, especially given the need to compare findings among studies conducted in different regions. Laboratory methods should incorporate analytical detection limits that are below relevant health-based benchmarks and odor thresholds, where feasible. If not feasible for all agents, investigators must provide a rationale for the investigators' selected detection limits and explain how they will interpret the data. Investigators must submit a plan for ensuring data quality and for protecting any confidential data (see *Data Management, Preservation, and Access Policy*).

Sampling locations relative to UOGD processes and potentially exposed communities. Many state regulatory programs include "setbacks" or "buffers" that must be maintained between UOGD and some sensitive land uses (e.g., residential areas and schools). For this reason, HEI-Energy has an interest in understanding the spatial extent of air-related exposures that might arise from UOGD. Sampling could occur anywhere from a specific piece of equipment on a well pad, to various distances from the fence line, to monitoring in nearby communities. However, as one moves away from the UOGD operation, it becomes more difficult, if not impossible, to isolate an exposure from UOGD from other sources. Therefore, investigators must justify their choice of sampling locations and approaches to allow for both

[6] The FracFocus database (www.fracfocus.org) is a publicly available database managed by the Groundwater Protection Council (GWPC) and Interstate Oil and Gas Compact Commission (IOGCC).
[7] Flowback is the fracturing fluid that returns to the surface through the wellbore during and after a hydraulic treatment. (Source: The Geological Society of America 2019)

an accurate assessment of exposure attributable to UOGD and an understanding of the spatial extent of exposures that might present a concern for health.

For water quality research that involves collection of original data, sampling approaches should align with the general requirements provided here for air quality research.

Sampling frequency and duration. Sampling programs should be designed to provide an understanding of potential exposures of acute duration (hours to weeks) and chronic duration (years).

Modeling. It is not feasible to measure releases from each and every UOGD process across many regions. Therefore, air and water measurements (from existing or original data) would likely be combined with atmospheric (RFA 20-1) or hydrological (RFA 20-2) modeling to relate emissions from unmonitored sites to surrounding concentrations for use in broader scale exposure modeling. A particular interest would be capturing the temporally and spatially varying concentrations of chemicals of concern over a range of environmental conditions. The Investigators should explain how proposed modeling will complement existing data and proposed original sampling programs to address this challenge.

Decision Framework to Guide Data Collection and Interpretation of Findings

Before research and sample collection begins, study designs must be carefully conceived, with objectives and specific plans for modeling and for data collection, statistical analysis, and an approach to interpreting study results. Investigators need to develop a framework that defines and guides decisions at key points once the research begins. Such a framework will ensure that research progresses efficiently and transparently with respect to the research itself and also communication of findings.

Investigators must include a Decision Framework in their proposals that addresses the topics described below, recognizing that some detail cannot be provided at the proposal phase but will need to be provided once final study designs have been established. A decision tree outlining the framework would be welcome.

Data Collection and Analysis. HEI-Energy expects investigators to specify their Decision Framework before data collection begins. It should specify how the investigators will sequence data collection and analysis in a manner that maintains focus on important potential exposures, while ensuring the efficient use of resources. For example, investigators might choose to study a longer list of chemical analytes or a broader geographic area in an early phase of research and define and use specific criteria for reducing the number of chemical analytes or the geographic scope. Investigators should describe how interim analyses of data will inform the following phase of data collection (i.e., building on the previous phase of data collection). Investigators should integrate this Framework into their quality assurance plan throughout all phases of research (described below under “Quality Assurance”).

Scientific Interpretation of Results. The investigators should explain how they will integrate study findings to describe the type, magnitude, and likely sources of observed exposures associated with UOGD processes. The integrated analysis should address the representativeness and generalizability of the findings, the relevance of the observed exposures under future conditions and, where possible, the potential effect of source or exposure mitigation measures. Where feasible, results should be interpreted in light of the fraction of UOGD operations or locations represented by study results. HEI-Energy expects investigators to specify their technical decision framework for determining the utility of continued exposure research or future health research based on their findings.

Health Risk-Based Interpretation of Results for Communities in Study Locations. In the Decision Framework, HEI-Energy expects investigators to specify their plan for interpreting and communicating

interim and final results in the context of health risk for communities living in their study locations. Investigators should integrate this framework into their broader Stakeholder Engagement Plan (see "Engaging with Communities and other Stakeholders") and cross-reference the Stakeholder Engagement Plan where applicable.

Investigators must be willing to work with HEI-Energy and other funded research teams before research commences to further refine and harmonize their approach to performing analyses, reporting and interpreting interim and final results, and communicating interim and final results to interested stakeholders.

Quality Assurance

To ensure research of the highest quality, all work will be subject to Research Committee oversight, including quality assurance audits, guidance from ad hoc panels of external experts, and peer review by the HEI Energy Research Committee (visit *HEI-Energy Process*). However, quality assurance depends primarily on the investigator's own quality assurance plan throughout all phases of research. In the full application process, investigators must provide an overarching explanation of their quality assurance and management plan. Before commencing research, investigators must prepare and obtain approval of a Quality Assurance Project Plan (QAPP) prepared in accordance with U.S. EPA guidance (see http://www.epa.gov/quality).

Innovative Methods

The key features of a study design described above are meant to help guide, not restrain, applicants from designing innovative research that meets the overall goals and objectives of the RFA. The examples noted are provided to help inform potential research teams.

RESEARCH TEAM

The research team should possess the full range of expertise to conduct the proposed research. The Principal Investigator (PI) must be a widely recognized expert in their area(s) of expertise with a reputation for producing high-quality and objective research. The PI should be affiliated with an established research organization, be extensively published in the peer-reviewed scientific literature, and have demonstrated experience successfully leading multidisciplinary teams of scientists, ideally in the context of community-engaged research.

The full team may include the PI, their immediate team (other faculty, research scientists, post docs, students, and technicians), co-PI(s) or collaborator(s) at other institutions, and consultants. The team should include members with expertise needed to implement the proposed research, including exposure assessment, biostatistics, environmental monitoring and modeling methodologies, the UOGD processes under study, health-related expertise needed to inform study design and to interpret exposure findings for communities in the study area, risk communication, and stakeholder engagement.

HEI strongly encourages applicants to diversify their research teams by including individuals from groups that are underrepresented in environmental exposure and health research and, to the extent appropriate given the study location(s), attuned to and knowledgeable about the communities in which the studies are taking 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[8].

The team's technical proposal ideally will be informed by engagement with experts representing multiple sectors (e.g., academia, communities, regulatory and public health agencies, industry, and NGOs) and will include them in research as appropriate. The team will need to engage with study area communities and other stakeholders before, during, and at the completion of research; therefore, they should have demonstrated experience successfully working with stakeholders, including potentially affected communities.

The technical proposal must include an ***organizational chart*** that clearly identifies each team member, their affiliation and role in the research, and lines of communication among team members and how they lead to the PI who oversees the research and coordinates its successful completion within and across regions.

The team should have access to study sites (as evidenced by letters of support from site owners in the proposal, if needed) and have access to or be able to purchase facilities, equipment, and instrumentation needed to support the proposed research and have prior experience with preparing and implementing quality assurance plans.

If investigators plan to use data 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. A letter from the investigator who owns the data should be submitted with the proposal, stating his or her willingness to share the data with the applicant and with HEI-Energy, if requested (see the "Provision of Access to Data Underlying Funded Studies" under the HEI-Energy *Policy on Data Management, Preservation and Access*). Applicants should also discuss whether they will need to obtain IRB approval. In addition, the full application should include a plan for data sharing and accessibility at the end of the study (see *Policy on Data Management, Preservation and Access*).

For RFA E20-1, HEI expects to fund air quality research pertaining to multiple regions of the United States and may fund teams to work in one or more regions. HEI-Energy seeks consistency in the study design and implementation across regions to allow for comparisons and to improve understanding of variability in exposure across oil and natural gas-producing regions. Successful applicants proposing research in multiple regions should demonstrate an ability to coordinate research efficiently and consistently among study locations. Successful applicants proposing research in a single region should demonstrate an ability to coordinate successfully with other institutions and must be willing to work with HEI-Energy to coordinate study designs to ensure consistency across study locations during the contracting phase of research.

[8] 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).

Engaging with Communities and Other Stakeholders

HEI-Energy seeks research that is useful for government and industry decision-making related to UOGD. Proposed research also should bring clear value to the people living in communities affected by UOGD and other stakeholders. Other stakeholders can include regulators and public health officials at all levels of government, health and safety professionals within the oil and gas industry, and experts from environmental and public health non-governmental organizations.

Depending on the scope of research, HEI-Energy foresees the need to host workshops in each study area before research begins so that the research team can meet with communities in study areas to provide notice about the study, describe the research plan, answer questions, and discuss concerns. The primary goal for these workshops is to hear from community members and ensure that they understand the research and its objectives. This understanding will equip community members with the knowledge needed to comprehend the study results. Engagement would continue at key intervals during research to provide updates and, as appropriate, interim findings, and it would end after research is complete and final results have been communicated effectively. The Research Committee will work with investigators to develop and implement plans for communicating interim and final results.

Research that involves communities spread across large geographic areas might require other forms of stakeholder engagement (e.g., webinars) to encourage extensive participation.

Proposals must include a two-page outline describing a ***Stakeholder Engagement Plan*** for effective multi-directional communication with communities living in areas proposed for study as well as other stakeholders that have an interest in the proposed research. The outline should provide a framework describing:

- Research team members with the expertise and responsibility to implement the plan;
- Anticipated stakeholder groups and the approach that will be used to identify interested community members in the study area and other stakeholders;
- Communication strategies to optimize constructive stakeholder engagement and to foster relationships among the research team, community members, industry representatives, government officials, and other local stakeholders;
- Approach to ensuring that research translation and communication of study designs and results occurs through culturally appropriate means;
- Plans for effective engagement at key intervals during the research program; and
- Expected outcomes from implementation of the Stakeholder Engagement Plan.

Data Management, Preservation, and Access

Providing access to data is an important element in ensuring scientific credibility and transparency. Investigators must plan, conduct, and communicate research in accordance with HEI-Energy's *Policy on Data Management, Preservation and Access* to ensure the accessibility of data and information related to research, while maintaining confidentiality.

HEI-Energy's policy is 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 may have participated in the study and respects the intellectual interests of the investigators who conducted the study and other parties that may have shared confidential business information or proprietary data to enhance the research effort.

HEI-Energy expects the exposure assessment estimates and approaches generated under this solicitation to be made publicly available for use in the future. Applicants will be expected to include a ***plan for data sharing and accessibility*** at the end of the study. Where data are provided by a third party, a process for other investigators to obtain and work with the data should be described.

Study Duration and Budget

For RFA E20-1, HEI-Energy would anticipate funding two to four studies of 3 years duration, each conducted in one or more regions. HEI-Energy anticipates a maximum award per study of $2,500,000. HEI-Energy's review process will include consideration of proposed study location across applications to ensure that funded research collectively improves understanding of variability in exposure conditions among regions of the United States.

For RFA E20-2, HEI-Energy seeks innovative analyses of existing data and empirical research that involves collecting original data.

- HEI-Energy would anticipate funding two to six studies involving analysis of existing data. The studies would be limited to 1.5 years duration, with a maximum award per study of $250,000.
- HEI-Energy would anticipate funding one to two studies involving new empirical research and data collection. The studies would be limited to 1 to 2 years duration, with a maximum award of $1,000,000.

Application Process and Deadlines

The submission and review of applications for RFA E20-1 and RFA E20-2 will entail a two-stage process.

- Investigators submit a Preliminary Application by **September 24, 2020**. The Energy Research Committee will discuss the preliminary applications and invite a limited number of investigators to submit a full application. Feedback will be provided in **November 2020**.
- Invited investigators should submit a Full Application in **January 2021**. Full applications will be reviewed by a Special Review Panel before consideration by the Energy Research Committee.

HEI-Energy will host a **webinar on August 20, 2020** to provide an overview of this solicitation and answer questions from potential applicants. For more information and to register, go to https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2.

Eligibility

Researchers with advanced degrees (PhD, MD, or equivalent) who are affiliated with an established research organization can apply for funding. We welcome applications from researchers in the United States and elsewhere, as long as the proposed research targets the objectives provided in this RFA.

Preliminary Application

For instructions for completing the Preliminary Application, consult the "Instructions for Completing the Application" file (https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2).

Project Plan. Preliminary applications provide a brief description of the proposed research, including the overall goal of and rationale for the study, the hypothesis to be tested, specific aims, study design, exposure data that will be used in or generated by the research, and an overview of plans for data collection and analytical methods. The application should also include a discussion of how the proposed

research will contribute to the objectives of the RFA and satisfy the evaluation criteria specified below in "Evaluation Process for Full Applications."

Expertise and Budget. The preliminary application should specify the expertise and experience of anticipated collaborators and a brief description of how their expertise would contribute to designing and conducting the study, including coordination of research across regions, experience with field work and engaging with communities in study areas, 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.

Submission and Deadline. Preliminary applications should be submitted to Janet McGovern electronically at energyfunding@healtheffects.org by **September 24, 2020**. Once the application has been submitted, please send a second email to energyfunding@healtheffects.org without any attachments to notify HEI-Energy that your application has been submitted. HEI-Energy will acknowledge receipt of the preliminary applications. A complete preliminary application consists of:

- Preliminary Application form (available for download at https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2) that shall not exceed four pages, excluding references, using at least 11-point font size and 1-inch margins, and
- Brief (2-page) curricula vitae of the principal investigator and each of the co-investigators using the form provided.

Preliminary applications will be discussed at a meeting of the HEI-Energy Research Committee and assessed using the same criteria used to evaluate full applications. Questions about applications should be directed to Donna Vorhees (dvorhees@healtheffects.org). Investigators will be informed whether or not to submit a full application after the HEI-Energy Research Committee has considered the preliminary application.

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.

Submission and Deadline. Invited full applications should be submitted to Janet McGovern electronically at energyfunding@healtheffects.org. Applications should not exceed a file size of 20 MB. Once the application has been submitted, please send a second email to energyfunding@healtheffects.org without any attachments to notify HEI-Energy that your application has been submitted. HEI-Energy will acknowledge receipt of the full application. Full applications without pre-submission of a preliminary application and invitation from the Energy Research Committee will not be considered.

All forms are available for download at https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2. For instructions for completing each form, consult the "Instructions for Completing the Application" file (https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2). The application forms should be submitted as a single file in PDF format with appropriate bookmarks.

Applications will initially be reviewed by an external Special Review Panel using the evaluation process described below for full applications. The HEI-Energy Research Committee will discuss the applications favorably reviewed by the Special Review Panel in **May 2021**. Applicants will be notified about the funding decision in **June 2021**.

Evaluation Process for Full Applications

Criteria for Evaluation. Full applications will be evaluated in a two-stage process: an external review followed by an internal review. In both stages, applications are evaluated using the following criteria.

- **Relevance** to the objectives of the RFA.
- **Scientific merit** with respect to study design, methodology for collection and analysis of existing and original data, approach to modeling and evaluation of data, and overall quality assurance.
- Alignment of the proposed research with the following **key features**:
  - Determines whether an exposure pathway links a UOGD process with a community. Links one or more chemical or non-chemical agents directly released to the environment from a UOGD process to a potentially exposed community. The research allows for the detection of possible causal links between one or more UOGD processes (e.g., specific equipment, activity, or phase of development) and resulting human exposures. The study is designed to distinguish between agents released from UOGD and non-UOGD sources.
  - Useful for assessing health risk. Collects data or analyzes existing data (or establishes practical exposure assessment methodologies) that is useful for assessing the potential for human health effects at resolutions relevant for application in an epidemiology study or risk assessment.
  - Expands understanding of temporal and spatial variability of exposure. Selected study locations and designs will substantially fill important gaps in understanding of variability in exposure conditions over temporal and spatial scales relevant for decision making by communities, regulators, industry, and other stakeholders.
  - Broadly generalizable. Designed to be broadly generalizable across geographic regions, UOGD operating conditions, or communities over time, including periods of low and high UOGD activity, without sacrificing validity.
  - Optimizes use of the research budget by maximizing efficiency. Ensures that the research budget is spent on gathering data and information that is not already available (e.g., by incorporating or complementing existing data and information) and that prioritization and sequencing of data collection maintains a focus on exposures of possible concern.
  - Brings value to and informs decision-making. Is useful to communities in study areas, government officials, industry, and other stakeholders. Ideal study designs will be informed by a team attuned to and capable of engaging successfully with the communities in study areas and other stakeholders.
- **Experience, competence, and diversity of the research team**, including principal investigator, scientific staff, and collaborating investigators. Adequate time is allocated to each member of the team to allow for successful implementation of the proposed research and stakeholder engagement.
- **Adequacy of facilities**, including:
  - Access to study sites, instrumentation, and relevant data sets,
  - Adequacy and validity of facilities to implement the proposed research.
- **Reasonableness of the proposed budget**.

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

HEI-Energy invites external reviewers to serve on the Special Review Panel 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-Energy Staff screen reviewers for potential conflicts of interest with other applicants who have submitted a proposal under the same solicitation.

Internal Review. The internal review is conducted by the HEI-Energy Research Committee and generally focuses on the applications ranked highly by the Special Review Panel. The review is intended to ensure that funded studies constitute a coherent program addressing the objectives of HEI-Energy. The HEI-Energy Research Committee makes recommendations regarding funding of studies to the Board of Directors, which makes the final decision. These decisions are final and not subject to appeal by the applicant.

Conflicts of Interest. HEI-Energy's *Policy on Conflicts of Interest* specifies procedures that are similar to the guidelines set forth by the National Institutes of Health. Members of HEI-Energy's sponsor community are excluded from participating in solicitation development, applying for support, application review, and funding decisions.

This peer review system relies on the professionalism of each reviewer, Review Panel member, Research Committee member to declare to HEI-Energy the existence of any real or apparent conflict of interest. Reviewers who feel unable to provide objective advice for any other reason are expected to recuse themselves from the review of the application(s) at issue.

These RFAs were posted at http://www.hei-energy.org on **August 6**, 2020.

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