



A Health Effects
Institute Affiliate

Implementation Plan for a National Energy Research Program

April 2020

Trusted Science, Clean Environment, Better Health

HEI-Energy

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Implementation Plan for a National Energy Research Program

Health Effects Institute–Energy
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TRUSTED SCIENCE, CLEAN ENVIRONMENT, BETTER HEALTH

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ABOUT HEI-ENERGY

The Health Effects Institute–Energy was formed to provide a multiyear national research program to identify and conduct high-priority research on potential population exposures and health effects from development of oil and natural gas from shale and other unconventional resources (UOGD) across the United States. HEI-Energy plans to support population-level exposure research in multiple regions of the United States. To enable exposure research planning, HEI-Energy conducts periodic reviews of the relevant scientific literature. Once initial research is completed, HEI-Energy will assess the results to identify additional high-priority exposure research needs and, where feasible and appropriate, health research needs for funding in subsequent years.

The scientific review and research provided by HEI-Energy will contribute high-quality and credible science to the public debate about UOGD and provide needed support for decisions about how best to protect public health. To achieve this goal, HEI-Energy has put into place a governance structure that mirrors the one successfully employed for nearly forty years by its parent organization, the Health Effects Institute (HEI), with several critical features:

- Receives balanced funding from the U.S. Environmental Protection Agency under a contract that funds HEI-Energy exclusively, and from the oil and natural gas industry. Other public and private organizations periodically provide support;
- Independent Board of Directors consisting of leaders in science and policy who are committed to fostering the public–private partnership that is central to the organization;
- A research program that is governed independently by individuals having no direct ties to, or interests in, sponsor organizations;
- HEI-Energy Research Committee consisting of members who are internationally recognized experts in one or more subject areas relevant to the Committee’s work, have demonstrated their ability to conduct and review scientific research impartially, and have been vetted to avoid conflicts of interest;
- Research that undergoes rigorous peer review by HEI-Energy’s Review Committee. This committee will not be involved in the selection and oversight of HEI-Energy studies;
- Staff and committees that participate in open and extensive stakeholder engagement before, during, and after research, and communicate all results in the context of other relevant research;
- HEI-Energy makes publicly available all literature reviews and original research that it funds and provides summaries written for a general audience; and
- Without advocating policy positions, HEI-Energy provides impartial science, targeted to make better-informed decisions.

HEI-Energy is a separately funded affiliate of the Health Effects Institute (www.healtheffects.org).

THE NEED FOR TRUSTED SCIENCE

The Health Effects Institute's (HEI) Special Scientific Committee on Unconventional Oil and Gas Development published a *Strategic Research Agenda* - a broad multidisciplinary guide for future research about potential adverse impacts from the onshore development of unconventional oil and natural gas resources (UOGD)¹ in the Appalachian Basin and elsewhere in the United States (HEI 2015). The Research Agenda, as a blueprint for this national *Implementation Plan*, recommends research to better understand and to prevent or minimize potential adverse impacts from all UOGD operational phases.

The Committee recognized that UOGD provides important energy and other benefits. At the same time, the rapid escalation of these activities has raised questions about potential impacts in the communities where they are occurring. After extensive consultation with stakeholders and leading agencies, it has become clear that many of the important topics identified in the Research Agenda (e.g., occupational exposures and health, and most effective practices, such as wellbore integrity) are best taken up by the agencies and organizations that have the most relevant knowledge and experience (e.g., the National Institute for Occupational Safety and Health and the Department of Energy National Engineering and Technology Laboratory).

Other topics, notably those related to understanding human exposure and health effects, are receiving research attention, but a comprehensive program of integrated research, review, and communication is needed (HEI Energy Research Committee 2019a, 2019b). Consequently, questions about potential human exposures and health effects associated with UOGD persist and, given the controversy surrounding much of the science conducted to date, answering the questions will require a research program of the highest credibility, quality, and relevance. This *Implementation Plan* lays out just such a program to be undertaken by the Health Effects Institute – Energy (HEI-Energy), targeted at the most important human exposure and health questions with a well-established approach modeled after the one used for over 40 years by its parent organization, HEI.

AIMS OF A TARGETED RESEARCH PROGRAM

This *Implementation Plan* outlines a new national energy research program, focused initially on two critical topics:

- Targeted efforts to measure population exposures (such as from potential air and water exposure pathways), at representative unconventional oil and natural gas-producing regions across the United States, and
- As feasible and appropriate based on findings from the population exposure studies, targeted efforts to assess the potential health effects that might result from exposures.

¹ 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 of wastes (i.e., handling of waste from its creation to disposal, including collection, storage, transport, treatment, reuse, recycling, and disposal);
- production operations: extraction, gathering, processing, and field compression of gas; extraction and processing of oil and natural gas condensates; management of produced water and wastes; and construction and operation of field production facilities; and
- post-production: well closure and land reclamation.

With resource development projected to continue, alongside growing efforts to switch to renewables and conserve energy, a source of high-quality, impartial science is needed to support decisions about how best to ensure protection of public health in the oversight and implementation of this development. HEI-Energy anticipates that results from the energy research program will be seen as credible by a broad range of stakeholders and used by federal, state, and local regulators, the oil and natural gas industry, environmental organizations, public health experts, and other stakeholders to inform policy development in this important area.

Proposed research will be:

- Competitively selected for funding, overseen, and reviewed by experts who work independently of HEI-Energy's sponsors
- Carefully designed and of the highest quality
- Coordinated with past and ongoing research efforts for efficiency
- Informative on a regional and national scale with relevance to policy decision-making
- Responsive to technological innovation and changing industry practice, regulation, and market conditions while remaining consistent with this *Implementation Plan*.
- Focused on the most time-sensitive and critical issues
- Responsive to sponsor and stakeholder interests

This plan describes how HEI-Energy will organize to conduct this research to ensure maximum credibility and quality, communicate results for effective use in decision making, and evaluate the research program and strategically plan to ensure the effort is on track to achieve desired goals. It also describes the technical approach for selecting specific research topics for funding, a timeline for implementing the research, and an initial estimate of the resources necessary to implement research (Attachment A).

ORGANIZED TO DELIVER CREDIBLE, HIGH QUALITY RESULTS

This plan describes an energy research program with a primary goal of answering key questions as quickly as possible, while simultaneously attaining high standards of quality and credibility. Meeting this goal will require active engagement with sponsors and other stakeholders at critical intervals during implementation of the research program.

Principles for Maximum Credibility

High-quality research can be obtained in a number of ways. Given the complex and at times controversial circumstances in which UOGD science has been produced and discussed, implementation of this research program will be most credible to a broad range of stakeholders if it is funded and overseen in a manner that leads to impartial and relevant research. The success of the effort will depend strongly on cooperation among government, industry, and other stakeholders to create an environment of trust in which research can be conducted and the results can be relied on to support sound decision-making. This approach depends on four basic principles that have been the hallmark of HEI's ongoing success in providing credible science to inform decisions:

- *Independent Governance and Balanced Funding:* Governance of the research program is independent of its sponsors or other interested parties and managed by an impartial research organization. Core funding is balanced with sponsorship by industry and government.¹
- *High-Quality Science:* The research is overseen by a research committee and a separate review committee, each composed of leading scientists in various fields relevant to the research program. Members are vetted for bias² and conflicts of interest to ensure that the research and peer review of results are carried out impartially. The research committee selects studies for funding on a competitive basis. The review committee, not being involved in the selection, design, or oversight of the studies, comprehensively peer reviews all results of the studies for quality and technical rigor.
- *Open and Extensive Communication:* HEI-Energy communicates results widely and transparently, makes the underlying data available, and disseminates comprehensive reports — including all results, interpreted in the context of other research — to the widest possible audience at no cost.
- *No Advocacy:* The purpose of the independent research program is to produce the best science, targeted to make better informed decisions without advocating policy positions.

Structured as Part of HEI

To ensure the fastest possible start-up of research, and to maximize its credibility and impact, HEI-Energy's research program has been implemented within the existing HEI structure, albeit with dedicated leadership, staffing, and scientific oversight bringing the appropriate scientific skills. This approach builds on the longstanding track record of HEI by applying its successful model to questions that arise from UOGD, which include and extend beyond those of HEI's current air pollution research program. Specifically, the governance structure for the research program includes four primary elements:

HEI-Energy Board of Directors. HEI is led by an independent Board of Directors consisting of distinguished leaders from a range of policy and science disciplines, and with no direct ties to HEI's sponsors. The HEI Board must be approved by both government and industry sponsors after which they exercise independent oversight of the Institute. Their primary role is as guarantor of the independence and quality of HEI's scientific processes and products. The new Board of Directors for the energy research program ("Energy Board") has the same primary role of overseeing the integrity and independence of HEI-Energy's operation and scientific processes and products. Specific responsibilities include (1) appointing Research and Review Committees for the new research program, (2) assuring the absence of bias in, and impartiality of, all aspects of the research program, (3) ensuring the application of HEI's conflict of interest procedures and (4) providing high-level fiscal and governance oversight. The Energy Board is comprised of three existing HEI Board members, with the option of appointing two additional members, all with the knowledge required to oversee the Program. Consistent with HEI operation and principles, new Energy Board members will be appointed by the existing Board contingent on the approval of sponsors, having no direct ties to the sponsors or other important conflicts of interest, and being impartial in matters related to oil and gas development.

Scientific Committees. The Energy Board appoints leading independent scientists, from a range of relevant disciplines, to oversee all aspects of the research program, including two committees, patterned after the successful committee structure of HEI's air pollution research program:

¹ Occasionally, HEI-Energy receives financial support from foundations and other sources.

² HEI-Energy checks for evidence of bias by reviewing an individual's body of work for indications of bias, such as whether they are wedded to a specific point of view and disinclined, or reasonably believed to be disinclined, to consider other views or relevant evidence to the contrary.

- **Energy Research Committee:** The Energy Research Committee has principal responsibility for:
 - developing the overall research program,
 - drafting and issuing competitive Research Solicitations for research that are consistent with the goals and criteria specified in the *Implementation Plan*,
 - selecting investigators after vetting them for potential bias and conflicts of interest that might interfere with the integrity of the scientific work and interpretation of results, and
 - intensively overseeing the completion of research.

Oversight includes, among other things, site visits, audits of quality assurance and quality control, and review and approval of regular progress reports throughout the project. The Research Committee will include scientists with expertise in air and water quality, exposure assessment, hydrogeology, petroleum engineering, epidemiology, medicine, public health, toxicology, risk assessment, statistics, and other relevant disciplines.

- **Energy Review Committee:** The Energy Review Committee is separate and independent from the Energy Research Committee and has principal responsibility for peer review of research, including:
 - intensively reviewing comprehensive reports of all analyses conducted by investigators funded by HEI and HEI-Energy,
 - examining the research design and conduct, the statistical analysis, and the appropriateness of the conclusions drawn given the results, and
 - preparing its own commentary on the research reports, including their scientific contributions, limitations, and relevance to policy questions in the context of current and anticipated changes in UOGD technology and regulation.

The reports of the Review Committee include a concise Executive Summary designed to communicate clearly to both technical and lay audiences. The Review Committee will include experts with the same skills as the Research Committee, but who have had no part in the selection or oversight of the studies.

Members of these committees are selected by the Energy Board after determining that they possess the experience, expertise, and impartiality necessary to guide and ensure the quality of the research program such that results are broadly relevant and useful to sponsors and others making decisions about UOGD. Before committee members are appointed and annually thereafter, HEI-Energy obtains and evaluates a disclosure of conflicts of interest, public positions taken, and other relevant background, using a procedure similar to that employed by the National Academies of Science, to ensure that the members are able to review the research program objectively.

Implementation Plan. A key element of the HEI-Energy Approach is an *Implementation Plan* – developed with extensive input from sponsors and other key stakeholders – to guide all aspects of the research program.

Supplementary Expert Guidance. The Research Committee will identify the need for and appoint members of External Review Panels and ad hoc experts to support research planning and oversight:

- **External Review Panels:** External Review Panels are made up of independent scientists who have knowledge specific to individual Research Solicitations, which complements the knowledge of the Research Committee, and who do not have important conflicts of interest related to the applications under review. These panels are established by the Research Committee solely to evaluate and score the scientific merit of scientific applications submitted in response to Research Solicitations in order to inform the Committee’s funding decisions.

- Ad Hoc External Advisors: As needed, HEI-Energy will consult experts in other subject areas, such as petroleum chemistry and geology and trends in industry operational practices and regulatory frameworks. These consultations keep HEI-Energy and its expert committees apprised of changes in the rapidly evolving world of UOGD technology, practice, and regulation and how such changes relate to the potential for exposure now and in the future.

Active Engagement with Sponsors and Other Stakeholders

HEI-Energy's work gains the highest level of influence because of the care with which the science is competitively selected for funding, overseen, and reviewed by experts who work independently of its sponsors. However, the quality and relevance of that work is enhanced immeasurably by input from sponsors and other stakeholders at key points throughout the scientific process to ensure that the expertise that they can bring is incorporated on a regular basis. The stages of that process and the extent involvement are illustrated in Figure 1 and briefly summarized here.

Selection of Energy Board, Energy Research Committee, and Energy Review Committee Members.

The selection of Energy Board members was undertaken by the current HEI Board of Directors. The Energy Board of Directors selected members of the Research Committee and will select members of the Review Committee. Board and Committee members are selected after careful vetting of both expertise and any potential conflicts of interest or bias.

- Sponsors play an active role in the program by recommending and approving appointments to the HEI-Energy Board of Directors.
- Sponsors can recommend individuals for service on the Energy Research Committee and Energy Review Committee (not yet formed) and as ad hoc expert advisors.
- At times, members of sponsor government agencies and companies as well as other expert stakeholders may serve as advisors.

Implementation Plan: This *Implementation Plan* guides all science activities under the research program. The Research Committee is responsible for developing and overseeing the research program, which must be based on the *Implementation Plan*.

Development of the Plan benefited from the extensive input of sponsors and other stakeholders on upcoming policy and regulatory decisions, key technology developments, and priority studies that HEI-Energy should consider undertaking. Other stakeholders are also invited to provide input into the Plan during development (e.g., at workshops). Sponsors reviewed and commented on the draft *Implementation Plan* prior to it becoming final.

Research Planning and Selection: New Research Solicitations for priority topics flow from the *Implementation Plan*. The Research Committee drafts and issues each Research Solicitation, reviews applications with input from an External Review Panel with knowledge that is specific to each Research Solicitation, and selects investigators based on a range of considerations including scientific merit, relevance to the targeted information sought, and after vetting for any potential conflicts of interest or bias.

Throughout the implementation of the Plan, sponsors and other stakeholders have multiple opportunities to provide feedback, such as participation in research planning workshops and reviewing and commenting on draft Research Solicitations. They have the opportunity to provide further input during regular visits by HEI-Energy leadership to sponsor organizations and trade associations.

Identification of External Review Panel Members and Ad Hoc External Advisors: HEI-Energy anticipates the need for one or more External Review Panels and ad hoc external advisors on specific questions that might arise during research planning and implementation.

Sponsors are solicited for recommendations of experts to serve on External Review Panels or as ad hoc expert advisors. In addition, sometimes experts from sponsor organizations serve as advisors.

Periodic Research Oversight: The Energy Research Committee has sole responsibility for detailed oversight of research and its quality. However, there are opportunities for Sponsors to receive updates on research.

Sponsors and other stakeholders can participate in investigator workshops conducted by Energy Research Committee members and the investigators to discuss study progress and to engage with communities in study areas.

Report Review and Publication: As noted above, the intensive peer review of HEI-Energy Investigator reports by the Review Committee, and the Commentary the Review Committee prepares, are cornerstones of HEI-Energy's reputation for independence and credibility.

Although sponsors are not involved in that process, HEI-Energy sponsors are provided with advance notice, with report summaries and webinar briefings at least one week before public release of a report, ensuring that sponsors are fully informed of the research findings in advance.

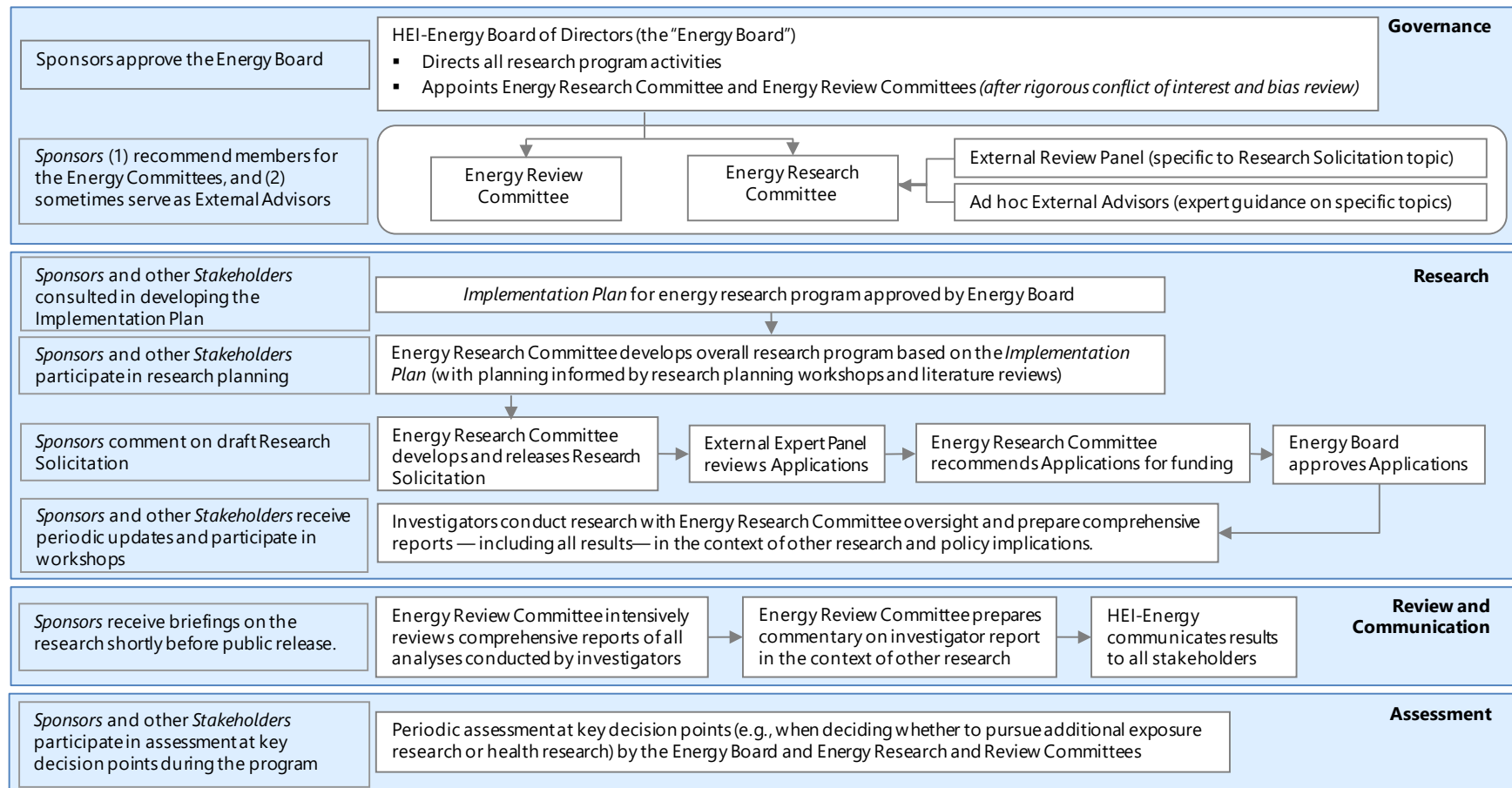
Assessment of the Research Program: HEI-Energy envisions three primary assessment points during the course of the program: (1) at and soon after two *Research Planning Workshops* to discuss research priorities, (2) at an Investigator workshops with the Energy Research Committee in the study areas to discuss progress and future needs, and (3) after exposure study findings are available to decide whether human health studies or additional exposure studies are warranted.

- Above and beyond the formal opportunities for assessment, sponsors and other stakeholders may choose to bring new issues to HEI-Energy's attention whenever they may arise.
- HEI-Energy discusses with sponsors any adjustments made to the *Implementation Plan* in response to new issues. Adjustments are made to ensure that HEI-Energy's work has the highest current relevance and must be consistent with the purpose of the research program.

COMMUNICATING RESEARCH FOR EFFECTIVE USE IN DECISION-MAKING

HEI-Energy was established to conduct credible, high-quality, policy-relevant research in controversial circumstances and communicate the results of such research to often competing interests. It has long recognized the importance of effective and strategic communication and successfully met that responsibility since its inception.

The best designed and implemented research program can go for naught if plans for effective communication of results to a wide variety of parties are not built in from the very start of the program. The credibility and acceptance of those results hinges on all major parties understanding where the research came from, and the care and independence with which it was conducted and reviewed. HEI has always pursued the philosophy that much of its work "begins, not ends, with the publication of a report," and the results of this important research program will require redoubled efforts to ensure at all stages that results are clearly and effectively communicated.

Figure 1. Overview of HEI-Energy's Energy Research Program and the Role of Sponsors and Other Stakeholders¹.

¹ While *Sponsors* and other *Stakeholders* contribute important expertise and knowledge at key intervals of HEI-Energy's research program, HEI-Energy and its Expert Committees have full responsibility for research selection, oversight, peer review, and reporting, all of which is conducted independently of sponsors.

Early Engagement

From the start of its research programs, HEI-Energy works with sponsors and its own broad network to identify key regulators, stakeholders, and opinion leaders at the federal, state and local levels. HEI-Energy will engage with key parties early in the research planning process and at important programmatic intervals so that their perspectives are understood, and the origin and priorities of the program are clear to all potential audiences. HEI-Energy engages personally both at the senior management and technical levels, building relationships and fostering confidence in HEI-Energy and its staff. As the research program proceeds, HEI-Energy will engage with sponsors and other knowledgeable parties often to identify emerging issues, constituencies, and decision makers in oil and natural gas-producing regions of the United States.

Periodic Updates

HEI-Energy works to ensure the widespread visibility of, and interest in, ongoing research. On a regular basis, HEI-Energy engages in open communication about studies that are underway, the investigators involved in each study, and when the studies are expected to be completed and undergo peer review.

Communication Vehicles and Forums

HEI has developed a range of communication vehicles for any type of study and its results, from simple 1-page summaries (“HEI Statements”), to press releases, the HEI Commentary, and comprehensive reports made available online and in print. Importantly, reporting of HEI research always places any positive findings in the full context of all results obtained by the investigators, the broader scientific literature, and new developments in regulation and technology. This comprehensive and impartial reporting is essential to ensure that any single finding is not over-interpreted.

The geographic, operational, and temporal relevance of all findings from this research program will be clearly enunciated. For example, HEI communications will explain the extent to which results reflect conditions across various regions, whether they are relevant to the entire UOGD industry or just a subset of UOGD operations, whether they are indicative of past, ongoing, or possible future conditions, and whether they reflect typical operating conditions or accidental conditions.

It will also be important to provide guidance on how results can be used effectively. For example, they might be useful to industry personnel who are charged with managing UOGD operations in a way that further ensures protection of nearby communities; they might be used to help federal, state, and local officials focus regulatory oversight, or they might help community members understand and respond to nearby UOGD operations.

HEI results are delivered by HEI senior management and scientific staff in multiple policy, technical, and public venues clearly and often. These include:

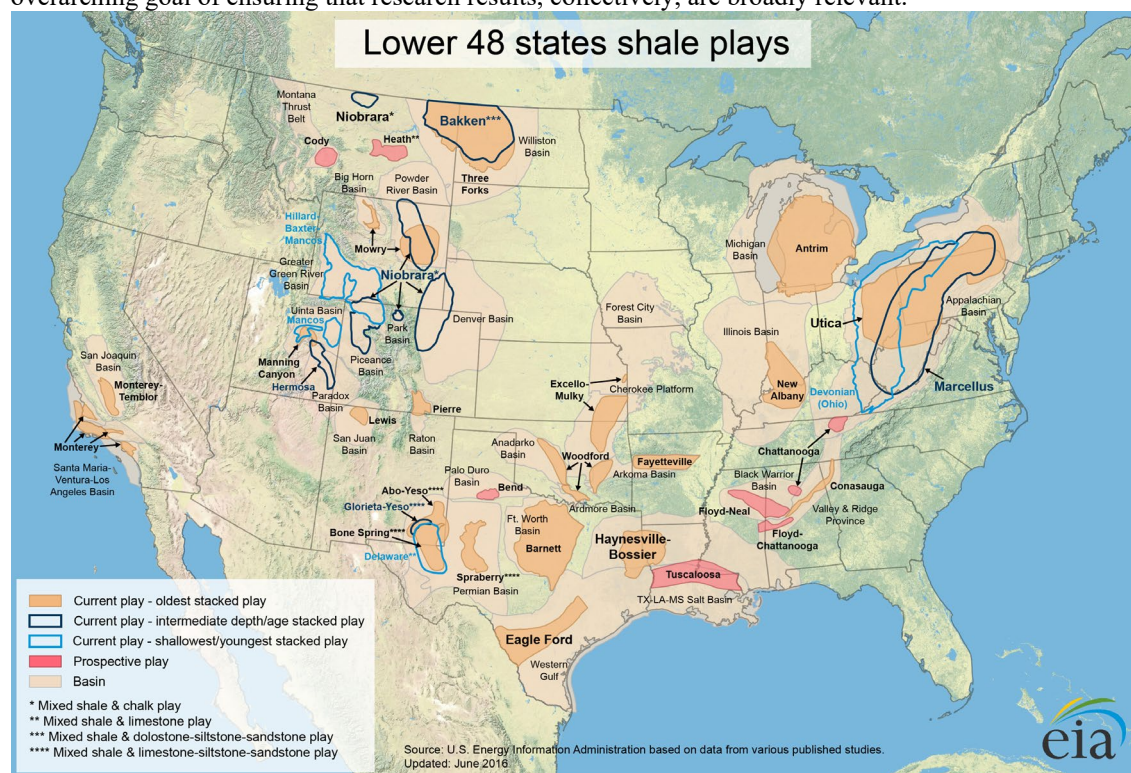
- Regulatory proceedings and in formal written comments
- Industry forums for senior decision makers, technical staff and trade associations
- Federal and State regulatory and governance associations
- Scientific forums (e.g., National Academy of Sciences)
- Congressional hearings
- Academic forums and technical workshops
- Press briefings and public meetings, among others

As noted above, HEI always provides sponsors with advance notice and briefing of all study results at least one week in advance of public release. For major studies, these briefings occur early enough to ensure that sponsors have time to prepare any relevant press or other communication response of their own. With these steps in place, research results can be communicated in a way that fosters their timely and effective use in decision-making.

IMPLEMENTING HIGH PRIORITY SCIENCE

HEI-Energy envisions that the research program will provide a better understanding of potential exposures¹, and whether any exposures could be consequential for the health of people in communities across important UOGD locations in the United States (Figure 2). This improved understanding will be useful for people living near UOGD operations who wonder about the potential for exposure and health effects, public officials charged with protecting public health, and UOGD industry personnel responsible for ensuring the safety of their operations. The results of this research program will also contribute to the broader national debate about energy policy by improving understanding about a prominent source of energy.

Figure 2. Oil and natural gas development from shale and other tight resources occurs across multiple regions in the U.S. and around the world. Research will be conducted in important oil and natural gas-producing regions with an overarching goal of ensuring that research results, collectively, are broadly relevant.



Origins of the New Energy Research Program

The research program represents the first step in implementing recommendations of HEI's Special Scientific Committee on Unconventional Oil and Gas Development in its *Strategic Research Agenda*

¹ Exposures that involve chemical concentrations or other agent levels that are within all applicable regulatory limits are not expected to be a primary focus of research.

(HEI 2015). The Special Committee recommended research to answer questions that collectively indicate knowledge gaps, are linked to the goal of better understanding and preventing or minimizing potential adverse impacts on human and ecological health and well-being, and apply broadly to UOGD regions in the United States. In addition to the research questions, the Special Committee concluded that study designs should account for and contribute to the understanding of several cross-cutting themes:

- Background conditions¹,
- Variability with respect to a number of factors (e.g., geology, industry practice across regions and over time, and human and ecological exposure and susceptibility),
- Releases to the environment under routine and unintended operational conditions, and
- Benefits of UOGD and their interrelationships with the impacts being studied.

The new research program's focus on potential human exposure and health effects reflects the high priority research topics from the Research Agenda that intersect with sponsor interests.

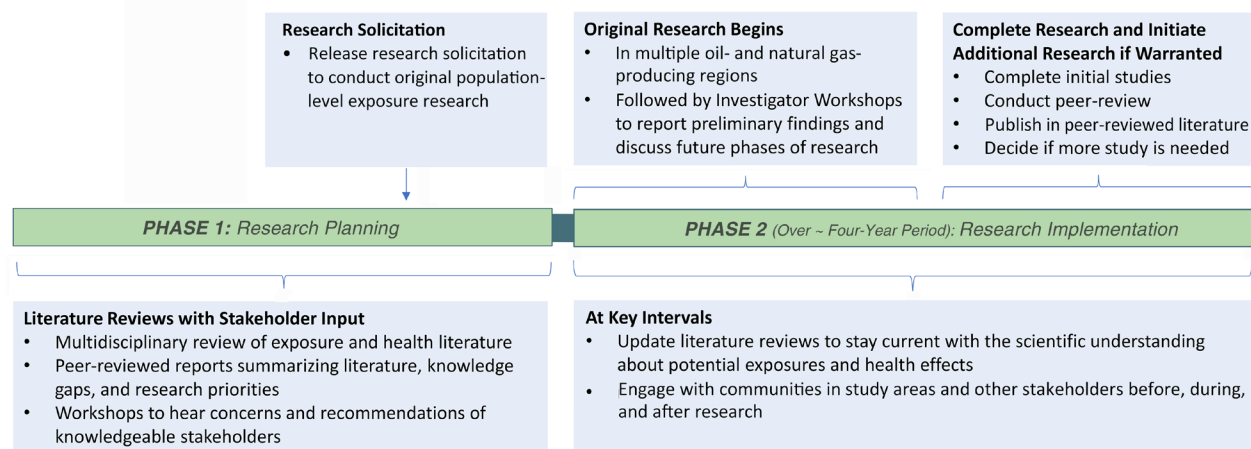
Overview of the Energy Research Program

This *Implementation Plan* focuses on two critical topics:

- Targeted efforts to measure population exposures (such as from potential air and water exposure pathways), at representative unconventional oil and natural gas-producing regions across the United States, and
- As feasible and appropriate based on findings from the population exposure studies, targeted efforts to assess the potential health effects that might result from exposures.

This section describes the major elements and products of the research program during its initial term, which are divided between two phases: (1) research planning and (2) research implementation (Figure 3). During the initial term, HEI-Energy will fund research on potential population exposures and does not anticipate funding research on potential health effects unless determined feasible and appropriate following completion of the exposure research and consultation with Sponsors.

Figure 3. Timeline for implementing the Energy Research Program and Major Products from its Initial Term.



¹ Background conditions are those that exist in the absence of UOGD operations. Examples include chemical concentrations in the environment originating from natural and anthropogenic sources other than UOGD, and baseline health characteristics of a potentially exposed population that need to be distinguished from potential UOGD effects. Study designs must account for these conditions to support conclusions about the sources of exposure that warrant research.

Research Planning

People in communities near UOGD might be exposed to chemicals, noise and other agents associated with UOGD (HEI-Energy 2019b). The term ‘agent’ refers to chemical (e.g., petroleum hydrocarbons), sensory (e.g., noise and light), biological, and psychosocial (e.g., emotional stress) agents with the potential to affect human health under some exposure conditions. The term ‘exposure’ denotes the way in which someone comes into contact with a UOGD agent over space and time, potentially through many pathways. Identifying potential UOGD agents and using rigorous methods to quantify the contributions of specific UOGD operations to exposure are essential for understanding potential health risks. The research program is expected to focus on chemical¹ and sensory agents, although assessment of other exposures will likely be important to any future assessment of health effects.

Much planning and preparation for the research program has been completed.

Strategic Research Agenda. Planning began with the HEI Special Committee’s preparation of the *Strategic Research Agenda* (HEI 2015). The Research Agenda was informed by the Special Committee’s extensive 1.5 year review of the peer-reviewed literature, consultations with a broad range of stakeholders and experts during three public workshops conducted in Pennsylvania and West Virginia, and a tour of drilling and hydraulic fracturing operations in Ohio.

Implementation Plan. This plan is based on recommendations made in the *Strategic Research Agenda* and guides all literature reviews, workshops, original research, and other work completed as part of the research program. It has undergone review by HEI-Energy sponsors prior to being finalized.

Energy Board of Directors and Energy Research Committee. The HEI Energy Board and Energy Research Committee have been appointed and have begun early work to develop the research program and plan for original population exposure research.

Tour of UOGD Operations. The Energy Research Committee toured UOGD operations in Weld County, CO, in July 2018. Committee members have a broad range of levels of familiarity with UOGD, and the tour provided an opportunity to familiarize members who had never observed these operations directly and expand the knowledge of members who had. HEI-Energy will organize future tours as needed to maintain an understanding of UOGD operations.

Research Planning Workshops. HEI-Energy conducted research planning workshops with participants representing federal, state, and local government, communities, nongovernmental organizations, industry, and academia. The first workshop was conducted in Boston, MA in January 2018 for the purpose of discussing the Energy Research Committee’s review of health literature related to UOGD. Two additional workshops were conducted at the outset of the Committee’s survey of exposure literature in July 2018 in Denver, Colorado and in September 2018 in Austin, Texas.

Materials for these and other workshops hosted by HEI-Energy are posted at its website (<https://hei-energy.org/meetings>). Posted materials include the agenda, background information, speaker biographies and slide presentations, participant list, and a report summarizing proceedings of the workshop.

¹Methane’s contribution to greenhouse gas emissions is already the subject of major national research programs. Therefore, this topic is beyond the scope of HEI-Energy’s research program, and methane is not expected to be a focus of study except where its measurement might be useful for understanding other potential UOGD exposures that warrant study.

The workshops provided opportunities for participants to engage in a collegial and productive exchange with the Committee and other meeting participants about HEI-Energy's plans for its literature reviews and identification of future research challenges and opportunities. Speakers and other workshop participants brought diverse knowledge and interests to the deliberations and varying goals for the type of research that will be done. They represented sponsor organizations, federal and state government, industry, academic research scientists, environmental and public health nongovernmental organizations, community organizations, and HEI-Energy's Committee and staff.

An efficient research program that answers important questions as quickly as possible, while not omitting essential steps for ensuring the validity of research results, should build on existing information. The speakers advanced this objective by providing a series of presentations summarizing relevant data and research about potential UOGD exposures, including both completed and ongoing research. Results and recommendations from both workshops were summarized in workshop summary reports, which the Research Committee used to help guide its preparation of the draft Research Solicitations.

Review of Health Literature. HEI-Energy released a final report, summarizing its systematic review of epidemiology studies about the potential health effects of UOGD (HEI-Energy 2019a). The review was designed to yield a transparent, reproducible, objective, and critical assessment, which underwent independent peer-review. The Committee evaluated the strengths and limitations of 25 studies that met inclusion criteria, and qualitatively assessed the studies and whether exposures originating directly from UOGD might have led to the assessed health outcomes. HEI-Energy produced a video and fact sheet for a general audience that summarized this review (<https://hei-energy.org/publication/potential-human-health-effects-associated-unconventional-oil-and-gas-development>) and also plans to publish a summary of the work in the peer-reviewed scientific literature.

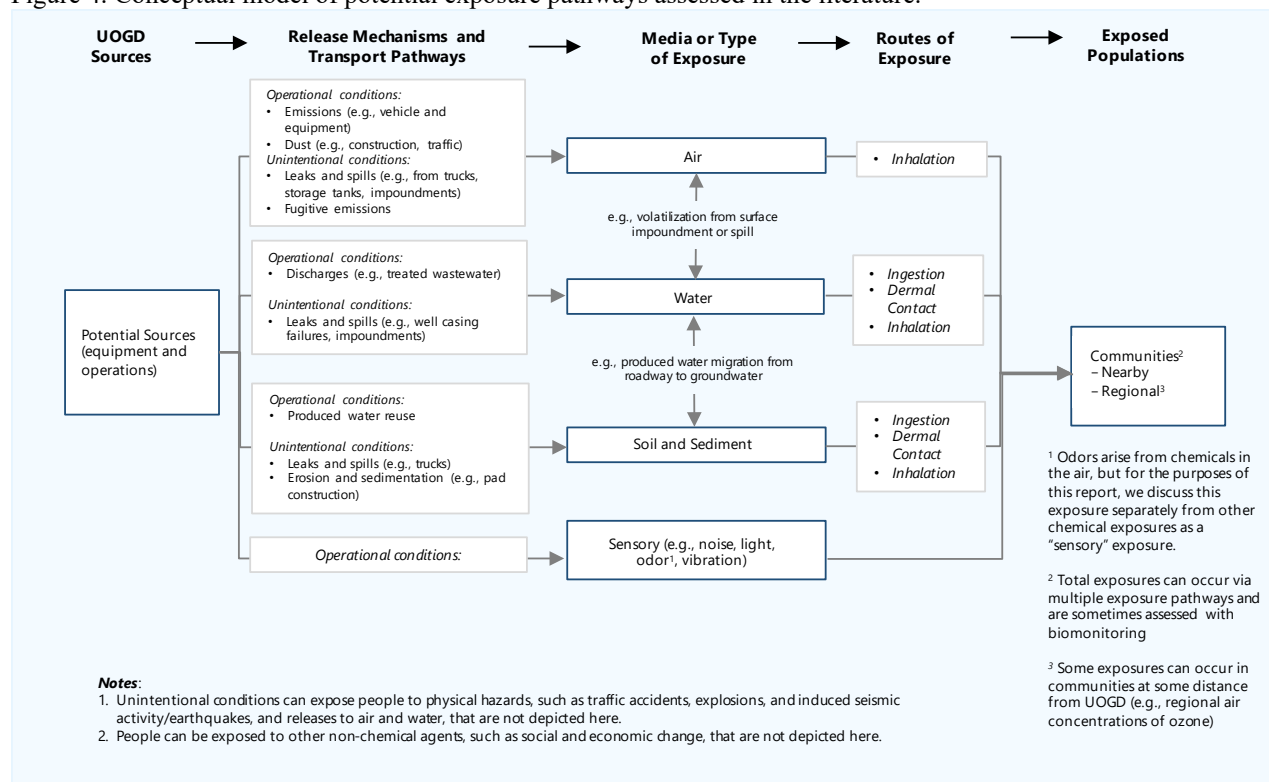
Survey of Exposure Literature. HEI-Energy released a draft report, summarizing its survey of studies about the potential exposures associated with UOGD (HEI-Energy 2019b). The survey included studies with diverse objectives that provide information about potential UOGD exposures. The goal was to understand who might be exposed, how exposures might arise, and how exposures vary over time and across regions. The survey was framed around a conceptual model of exposure to facilitate understanding of what is known about exposures and where knowledge gaps exist (Figure 4). Based on its survey, the Committee identified important gaps in knowledge and defined a set of characteristics critical to high-quality and policy-relevant research. HEI-Energy plans to publish a summary of the finalized version of this work in the peer-reviewed scientific literature.

Research Solicitation. HEI-Energy has prepared draft *Requests for Applications (RFAs)*, focused on a high priority subset of potential exposures shown in Figure 4, which it plans to finalize for public release in early 2020. The Research Solicitation seeks population exposure research in multiple U.S. regions. Its preparation was informed by the Energy Research Committee's own expertise, literature reviews, UOGD operation tours, and the three workshops. HEI-Energy will fund research that informs policy decisions about how best to protect public health in the oversight of UOGD. HEI-Energy expects that results will be used by federal, state, and local regulators, communities, the oil and natural gas industry, environmental organizations, public health experts, and other stakeholders to inform policy development in this important area.

The Research Solicitations will be distributed widely among the scientific community. HEI-Energy will be seeking multi-disciplinary teams with the skill and capacity to mobilize exposure studies at locations across the major oil and natural gas-producing regions of the country. Applications will be evaluated using pre-specified criteria and scored by External Review Panels specifically identified as having relevant expertise. The Research Committee will then make funding decisions based on the external review and their scientific judgment. Before research begins, HEI-Energy will negotiate detailed

contractual agreements with the research team and, as needed, with owners of facilities, operations, or equipment where some of the research may take place. The agreements will address a number of questions, including management of confidential business information, data access and dissemination, data quality assessment, cost management, insurance requirements, communication of results, and other factors important for successful implementation of research.

Figure 4. Conceptual model of potential exposure pathways assessed in the literature.



Public Presentation of Research Planning Products. HEI-Energy Staff and Energy Research Committee Members have presented early findings from the research planning phase at a number of professional gatherings and conferences, such as the International Society of Environmental Epidemiology, the Society for Risk Analysis, and HEI's Annual Conference. HEI-Energy expects these presentations to continue so that sponsors and other stakeholders are kept apprised of progress and interim findings.

Research Implementation

HEI-Energy anticipates funding research on potential population exposures in multiple regions of the United States.

Population Exposure Research

Scope of Research. HEI-Energy anticipates funding population exposure studies in at least two oil and natural gas-producing regions of the United States. Research will complement rather than duplicate well-designed research that has been completed or is underway. The goal will be to fund research that collectively contributes to a rigorous characterization of exposure under variable exposure conditions and locations, including identification of sources of exposure and careful consideration of cross-cutting themes (e.g., background conditions and whether exposure represents routine or unintended conditions).

HEI-Energy expects investigators to provide a Decision Framework to guide data collection and interpretation of findings as part of their proposals. This plan must specify their decision framework for sequencing data collection and analysis in a manner that maintains focus on important potential exposures, while ensuring the efficient use of resources. The framework should incorporate decision points for effective communication of findings in the contexts of health risk with communities in study areas and for determining the utility of continued exposure research or future health research.

Research proposals will be judged using explicit criteria specified in *RFAs*. One of the criteria will highlight the importance of and ease with which exposure research can be used to support potential future health research, should that be undertaken.

Workshops. HEI-Energy plans to conduct a series of workshops during implementation of research, with participation by the Energy Research Committee, sponsors, communities living in study areas, local authorities, and other stakeholders. Proceedings of all workshops will be summarized by HEI-Energy in a brief report that will be widely distributed while studies proceed, and results begin to undergo peer review and publication.

HEI-Energy will start by hosting *Regional Study Workshops* in each study area before research begins, providing an opportunity for workshop participants to learn about plans for research before it begins. After the first year of research, HEI-Energy will host *Investigator Workshops* to report preliminary findings, discuss whether any merit peer review and publication on their own, and make recommendations about modifications to the study design as warranted by findings from the first year of research. Sponsors, the Research Committee, and other workshop participants will have the opportunity to review initial findings and provide commentary before, during (by way of active participation), and after the *Investigator Workshops*.

Investigator Workshops will continue annually thereafter to report interim results until research is complete and ready to undergo review by the HEI-Energy Review Committee. At the final *Investigator Workshop* when final research results are presented, participants will have an opportunity to evaluate the results and make recommendations to the Energy Research Committee about whether additional exposure research is warranted beyond the initial term of the research program.

Integration of Exposure Study Results. When exposure studies are complete, investigators are required to submit a final report to HEI-Energy. The report provides an integrated view of the potential for UOGD exposures, including a summary of what has been learned about the likelihood of potential exposures. For exposures that have been observed, the report will summarize their type, magnitude, and significance, while carefully explaining the limits of their relevance and generalizability. For example, do they reflect routine or unintended operational conditions? Are they relevant to all or only a subset of operating conditions? Do they occur in only some regions or vary significantly across regions? What is their geographic extent beyond UOGD operational areas? Are they attributable in part, or entirely, to background conditions?

These studies will likely take place at, and around, specific operations in each representative region. To ensure transparency, HEI-Energy will need to have a mechanism for reporting the locale and types of facilities. In preparing reports for publication and communication of results; however, HEI-Energy will (a) consider whether any of the reported exposures might inadvertently communicate information regarded as proprietary by the operators of that site and take the necessary actions to avoid that disclosure, (b) ensure, as it always does, that results are presented in an integrated fashion and interpreted in light of knowledge about background conditions, and (c) otherwise comply with HEI-Energy's *Data Management, Preservation, and Access Policy*.

The draft version of the summary report will undergo independent peer-review by outside scientists and will be subjected to intensive review by the Energy Review Committee. The final report will be published alongside a Commentary, which summarizes the Energy Review Committee's evaluation of the study. Once finalized, HEI-Energy will provide pre-briefings to sponsors and share the report widely with federal and state agencies, industry, non-governmental organizations, and other stakeholders with an interest in the studies and their potential use in decision making.

Beginning with final reports from individually funded studies, the Energy Research Committee, with support from HEI-Energy staff, will prepare a brief report that integrates results from all studies.

Health Studies Where Warranted and Feasible Based on Results from Exposure Research

The Energy Research Committee conducted a systematic review of health literature related to UOGD in the United States (HEI-Energy 2019a). In its review, the Committee observed that the current body of epidemiological evidence represents an early phase in research geared toward understanding the potential health effects of UOGD. Many studies were well-designed and applied innovative methods to overcome data limitations that are common in observational studies of humans. Nevertheless, the Committee concluded that data and study limitations prevented it from determining whether exposures originating directly from UOGD contributed to the assessed health outcomes, either within individual studies or across the body of literature. Given the range of activities and chemicals to which populations surrounding UOGD are exposed, the Committee agreed that additional high-quality research needs to be undertaken to better understand the potential for human exposure and health effects from UOGD.

Are Health Studies Warranted and Feasible? The research program will include health studies only if findings from exposure studies indicate that they are warranted and feasible based on results from population exposure research after the initial term of this *Implementation Plan*. Any decision to pursue future health research would be based on the Energy Research Committee's review of exposure findings from the initial phase of the research program and would be made in consultation with sponsors and their interest and willingness to provide additional funding for such research.

As noted above, at the final *Investigator Workshop* when final exposure research results are presented, participants will have an opportunity to evaluate the results and make recommendations to the Energy Research Committee for further research, including health research to be conducted after the initial term of this *Implementation Plan*. Their recommendations — and the Research Committee's final decision — about health research will be based on the following criteria:

- High quality measures of exposure are available, and are associated with UOGD
- Exposure levels are sufficiently high or persistent to raise reasonable questions about the potential for adverse health effects in the exposed population
- The characteristics of the exposed population and the exposure itself are such that performance of a health study is feasible with sufficient statistical power to provide meaningful results. For example, UOGD occurs in some locations with very small populations, making it challenging, if not impossible, to investigate associations between UOGD and health outcomes, especially rare outcomes.

Prior to the final *Investigator Workshop*, the Research Committee might add to these criteria in consultation with sponsors to ensure that health research of the highest quality and relevance is pursued. To the extent feasible and necessary, any future health study funded under this research program should be paired with the exposure studies conducted under this *Implementation Plan* to ensure that it includes high-quality measures of both exposure and health outcome.

Desk Study Planning. Ideally, one would have a thorough understanding of exposure before pursuing any health study planning. However, there are some technical and practical reasons to begin planning for health studies even as exposure studies are underway. For example, it takes time to identify study populations and to determine whether they can be recruited (assuming that this step has not already been completed as part of an exposure study) and have characteristics important for achieving meaningful results. Specifically, the exposed population must be of sufficient size and must experience sufficient variability in exposure to be able to detect a relationship between the exposure and an adverse health effect, assuming that one were to exist. Thus, HEI-Energy will initiate identification of potentially exposed populations and appropriate designs for studies that could, if they ultimately move forward, determine if individuals exposed to UOGD are at increased risk for health effects. This effort will involve “desk study” only; HEI-Energy will not actively advertise or recruit study participants for a health study. This planning can be useful in determining whether exposure studies are focused on populations and locations amenable to meaningful study of potential health effects in a timely and efficient manner.

Design and Implementation of High-Quality Health Research. Studies comparing the incidence of adverse health outcomes simply in populations living “close to” and “far from” UOGD operations have limitations in resolving questions and concerns that have been raised about potential effects on human health. If health studies proceed, they will need to address important limitations of past studies related to exposure assessment and possible residual confounding. However, such studies can be complex, costly, and time-consuming; they should be pursued when their design is based on a strong, empirically based model of UOGD exposure and a plausible link between the UOGD exposure and adverse health outcomes.

Integration and Assessment of Health Studies. The integration and assessment of health studies would follow the same protocols as those described for the exposure studies (e.g., *Investigator Workshops*, peer review, integrative analysis, and effective communication of results). A third assessment point would likely be needed if health studies (or additional exposure studies) were pursued.

Fundamental Study Design Issues

Selecting High-Quality Research Proposals

The Energy Research Committee prepared the draft Research Solicitation with input from Sponsors (not yet complete) and other expert guidance. While exposure studies will address topics well within HEI-Energy’s expertise (exposure and health), a precursor to good study design is knowledge of the underlying UOGD operations and how they vary over space and time. The technical expertise of industry and regulatory sponsors, therefore, will be needed so that Research Solicitations seek the most useful and broadly relevant research.

HEI-Energy’s Technical Review of Research Proposals. HEI evaluates the quality of research proposals in two phases. First, an External Review Panel of scientists evaluates and scores the scientific merit of the applications according to criteria defined in the Research Solicitation. Second, the Research Committee evaluates the proposals with consideration of the External Review Panels’ evaluation and scores to determine whether the proposed research will (1) improve the understanding of the specific problem under investigation, (2) contribute to HEI’s overall research program, keeping in mind available resources, and (3) advance the goal of building a coordinated program of related studies designed to provide comprehensive answers to key questions, and not just completing a collection of independent studies. The Research Committee makes final recommendations regarding funding of studies to the Energy Board, which makes the final funding decision.

Check for Potential Bias. The Research Committee also evaluates the scientific objectivity of investigators by reviewing their body of work for indications of bias, such as whether the investigators are wedded to a specific point of view and disinclined, or reasonably believed to be disinclined, to consider other views or relevant evidence to the contrary. This evaluation of investigator scientific objectivity occurs as part of the scientific merit review and before funding is awarded.

Maximizing Representativeness and Generalizability of Research

Individual research proposals will be judged on a number of criteria related to their internal validity (e.g., sufficient power to discern desired difference in exposure, if any). Research will be prioritized that provides results that are highly representative of the population being studied. Representativeness means that a subset of a statistical population accurately reflects the members of the entire population in an unbiased way.

Beyond applicability of results to the population/regions under direct investigation, research will be prioritized that is applicable, or generalizable, to other populations. Such broad applicability is critically important given the rapid development of UOGD in many regions of the United States.

Sites investigated as part of the research program must provide a diverse representation of geography and basins under all operating conditions. In the end, results of studies must be interpreted in light of the fraction of UOGD operations or locations represented by study results.

Conducting Sound Research amid Fluctuating UOGD Activity and Evolving Technology, Practice, and Regulation

HEI has learned with its air pollution research that it must define a clear path forward while maintaining flexibility in its research program to anticipate and act on the unanticipated so that it can effectively provide useful results and respond to the needs of sponsors and others. This lesson is all the more important in a research program involving the rapidly changing technologies, regulation, and markets around UOGD. For example, as of the writing of this Plan, the US is currently experiencing a reduction in UOGD activity. The research program, therefore, must be designed with the cyclical nature of UOGD in mind. For example, periods of low UOGD activity might provide opportunities to characterize background conditions. Recognizing that UOGD activity could rise again, exposure studies conducted during periods of reduced UOGD activity should be designed in such a way that results can be reliably “scaled up” to reveal what they would be had sampling occurred during periods of higher UOGD activity. The strength of this approach is that it accounts for the fluctuating intensity of development. In addition, HEI-Energy will consult experts to stay apprised of UOGD technology, practice, and regulatory changes and how such changes relate to the potential for exposure.

Evaluating the Program to Ensure Achievement of Research Goals

HEI-Energy recognizes that the success of this research program will require its regular review, evaluation, and strategic planning to keep the research program on track to meet the desired goals. To foster program evaluation and strategic planning, HEI-Energy will:

- Assess and report on program progress and effectiveness on a regular basis,
 - Produce reports with integrated analysis of research results, and
 - Assess the cumulative results of the research program and their influence and provide the Energy Research Committee with advice on the need for additional exposure or health research.
- Additional research beyond the initial term of the research program

MAKING SUBSTANTIAL PROGRESS ON KEY QUESTIONS

The plan outlined here provides an opportunity to meet a vital need for rigorous and credible science to fill gaps in knowledge and understanding about potential exposure to and health effects from of UOGD. HEI-Energy envisions a locally informative and nationally relevant program of scientific review and targeted research, which is expected to make significant contributions to increased understanding and reduced uncertainty among regulators, industry, academics and the general public in key areas of concern. The success of the effort will depend strongly on cooperation among government, industry, and other stakeholders to create an environment of trust in which research can be conducted and results can be relied on to support sound decision-making.

The rapidly changing nature of the UOGD industry dictates the need for careful early planning to avoid research that might not have long-term relevance and frequent review thereafter to make sure that the research is on target to meet the goals defined in this *Implementation Plan*. Reliance on the HEI-Energy model will facilitate effective management of the research program by an existing team of seasoned executives and expert scientists with the experience and judgment to plan, oversee, conduct, review, and credibly communicate results that are relevant to governmental authorities, communities, health officials, industry, and other state and national stakeholders.

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ABBREVIATIONS AND OTHER TERMS

Agent	Refers to chemical (e.g., petroleum hydrocarbons), sensory (e.g., noise and light), biological, and psychosocial (e.g., emotional stress) agents with the potential to affect human health under some exposure conditions
Exposure	Denotes the way in which someone comes into contact with an agent over space and time, potentially through many pathways.
HEI	Health Effects Institute
HEI-Energy	Health Effects Institute - Energy
RFA	Request for Applications
UOGD	unconventional oil and gas development

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HEI-Energy convened the Energy Research Committee to conduct scientific reviews and oversee original research funded by HEI-Energy. The Committee is chaired by George M. Hornberger, Distinguished Professor of Civil and Environmental Engineering and of Earth and Environmental Science at Vanderbilt University and director of the Vanderbilt Institute for Energy and the Environment. Committee members are highly regarded experts in a variety of disciplines directly related to unconventional oil and natural gas development and its potential impacts. Special advisors and consultants contribute additional areas of expertise.

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