



---

## HEI-ENERGY RESEARCH AND REVIEW PROCESS

### INTRODUCTION

HEI-Energy is a nonprofit affiliate of the [Health Effects Institute](#) (HEI), chartered as an independent research organization to provide high-quality and impartial science about potential human exposure and health effects associated with onshore development of oil and natural gas from shale and other unconventional resources (UOGD) in the United States.

HEI-Energy receives funding from the U.S. Environmental Protection Agency and the oil and gas industry. Other public and private organizations periodically provide support. Sponsors will not be involved in selecting, overseeing, or evaluating research funded by HEI-Energy.

HEI-Energy's research program is guided by a five-year Implementation Plan, developed with input from HEI-Energy sponsors, other governmental and non-governmental organizations, the scientific community, and HEI-Energy's independent Board of Directors. The Board consists of leaders in science and policy who are committed to the public-private partnership that is central to HEI-Energy's work.

### RESEARCH AND REVIEW PROCESS

#### Overview

Two independent committees, the Energy Research Committee and the Energy Review Committee, work in an environment uniquely structured to foster the necessary separation between selecting and overseeing research and critically reviewing results. This separation allows HEI-Energy to fund and guide research, as well as provide credible peer review of that same research. Members of the scientific staff work closely with the committees to conduct HEI-Energy's business.

HEI-Energy has two main goals in funding research. One is to build a coherent research program for each set of related studies addressing questions in a more comprehensive way than would be possible with independent studies. Another is to provide timely, high-quality information to its sponsors and regulatory agencies for technological and regulatory decisions. In order to accomplish these goals, HEI-Energy works in a cooperative fashion with investigators and keeps in close contact with them through such means as progress reports, and workshops. The progress reports are reviewed by the HEI-Energy Research Committee and staff, and by outside experts, if deemed necessary by the Research Committee. In addition, HEI-Energy requires a comprehensive final report at the end of each study, which undergoes an in-depth review by the HEI-Energy Review Committee and additional experts.

HEI-Energy's research oversight and review processes are different from those at many other funding agencies. Please familiarize yourself with the requirements regarding scientific negotiation of project plans, the research agreement (contract), quality assurance program, progress reports, site visits, investigator workshops, final report, and publications, before applying. This section presents a brief summary of the research process, HEI-Energy oversight, and review process.

#### Research Committee

##### Research Development

The HEI-Energy Research Committee is an independent group of experts that is responsible for developing and overseeing Energy Research Program. This Committee consults with sponsors and other interested parties to determine research priorities and to develop the HEI-Energy Implementation Plan.

This Committee also conducts critical reviews of the health and exposure literature to identify knowledge and define research priorities.

Once the Research Committee has defined an area of inquiry, HEI-Energy issues the research solicitation to announce broadly to the scientific community that research applications are being sought.

#### Study Selection

The Research Committee will screen preliminary applications and invite chosen applicants to apply with a full application. Full applications will 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.

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

#### Study Oversight

##### *Contract Negotiation*

The Research Committee may request modifications in the project plan or budget before making a final funding recommendation to the Board. This approach enables HEI-Energy to mold diverse investigator-designed studies into a more coherent research program and to generate data more relevant to regulatory needs. HEI-Energy staff scientists act as liaisons between the Research Committee and investigators in this scientific negotiation process. The end-product is a project plan that is acceptable to both the investigator and Research Committee.

Upon satisfactory negotiation of the project plan and budget, a contract for the study is negotiated with the Principal Investigator's institution. HEI-Energy's Research Agreement is a cost-reimbursement contract rather than a grant. The contract contains a Statement of Work, which is an approved, brief description of work to be performed in each contract year, and the budget. Before studies commence, investigators should have a quality assurance / quality control plans and forms in place.

##### *Progress Reports*

Progress reports are due bi-annually at predefined intervals after study initiation, except during the final year when a comprehensive final report is due instead of the last progress report. The Energy Research Committee will review the progress report and provide feedback. Investigators address comments in a response letter or in the next progress report. The first progress reports of the year are used to check on general progress and provide an opportunity for timely feedback from the Energy Research Committee. The second progress reports of the year also provide an opportunity for feedback from the Energy Research Committee and form the basis for contract renewal for the following year. The second bi-annual report/renewal application provides information on progress in meeting the goals for that year, including the results. It also presents a plan and detailed budget for the subsequent year.

##### *Site Visits*

HEI-Energy will initiate a site visit to the investigator's laboratory to conduct a detailed scientific review and discuss progress, results, and the future course of work, and to discuss any concerns about progress or problems encountered during the study. Site visits are conducted by a few Energy Research Committee members, HEI-Energy scientific staff, and external expert consultants, as needed. Alternatively, webinars can be held if an in-person visit is not feasible.

## Review Committee

The final product of an HEI-Energy funded study is the Scientific Report. After the research has been completed, each HEI-funded Principal Investigator is required to prepare a comprehensive final report that describes the study and its findings. All HEI-Energy Scientific Reports are subjected to the highest standard of independent peer review.

The HEI-Energy Review Committee is not involved in the selection and oversight of HEI-Energy studies. It conducts a critical, in-depth evaluation of the final report once the study has been completed.

The Review Committee will assess the scientific quality of each investigator's report and evaluate the study's contribution to unresolved scientific questions. HEI-Energy will communicate the complete findings (both positive and negative) of the studies it funds in final reports, which will consist of the investigator's report and the Review Committee's commentary on the study. Commentaries discuss the strengths and limitations of the studies and put the findings into scientific and regulatory context.

With each report, HEI-Energy will also publish a Statement, written for non-scientists, that summarizes the scientific background and rationale for funding the study, the investigator's approach and methods, the key findings, and the Review Committee's interpretation of the study.

HEI-Energy will publish the reports and commentaries and make them available to the public at no charge.

## CONFLICT OF INTEREST

A robust policy on disclosure and management of relevant affiliations, relationships, and financial interests is essential. HEI-Energy has set out policies for disclosure of such "conflicts" — whether actual or perceived, financial, or otherwise. It uses these policies when reviewing applications, inviting peer-reviewers and advisors, and forming committees.