

INVESTIGATOR COMMITMENTS

HEI-Energy's research oversight and review processes are different from those at many other funding agencies. Please familiarize yourself with the requirements before applying. This page contains information about the scientific negotiation of project plans, the research agreement (contract), quality assurance program, progress reports, site visits, final report, and publications.

GOALS OF HEI-ENERGY OVERSIGHT

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.

The purpose of this section is to provide information to prospective applicants about HEI-Energy's management of studies and about the process for review and publication of final reports from HEI-Energy-funded studies. Applicants should read this section carefully to ensure that they understand the commitments in conducting studies with HEI-Energy funding.

SCIENTIFIC NEGOTIATION OF PROJECT PLANS

The Research Committee may request modifications in the project plan or budget before making a final funding recommendation to the HEI-Energy Board of Directors. For example, the Research Committee may request deletion of parts of the proposed project that are less relevant to HEI-Energy's objectives or overlap considerably with other studies; sometimes changes in the range of exposure concentrations of pollutants are recommended to make them more representative of ambient conditions. 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.

Research Agreement (Contract)

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.** Investigators should be aware that scientific and administrative contract negotiations may sometimes extend through a period of several months, which may result in changes in the scope or cost of the proposed study; therefore, certain portions of the applications may have to be updated prior to contract signing. In general, HEI-Energy requires that any significant changes in personnel, scope of work, and/or budget be reflected via submission of revised budgets, project plans, or other appropriate application materials prior to the signing of the contract. All studies should have a quality assurance / quality control plan in place. For human studies and major animal studies with expected regulatory significance, a written protocol should be approved by the appropriate institutional review boards before the study starts (see *Studies Involving Human Participants* and *Quality Assurance* below).

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. The scope of the research conducted by the investigator should be consistent with the Statement of Work. If results suggest new directions for research, however, the contract may be amended to allow changes in the Statement of Work upon written agreement between the investigator's institution and HEI-Energy.

Contracts are usually issued for one year, although HEI-Energy expects to provide support for the number of years initially approved by the Research Committee, provided work is progressing satisfactorily. The Research Agreement has been designed to maximize the integrity of the scientific process while providing needed protections and meeting applicable federal regulations. Once a contract is signed by both parties, an Abstract and Statement of Work written by the principal investigator may be distributed to the Institute's sponsors. These also will be available to members of the public who request them.

No work should be started nor should any study costs be incurred prior to signing of the contract unless explicit written authorization is provided in advance by HEI-Energy's Director of Finance and Administration.

STUDIES INVOLVING HUMAN PARTICIPANTS

As mentioned in the *Instructions for Completing the Application, Additional Submissions*, the applicant must submit, with the application, a written assurance for compliance with the guidelines established by the Environmental Protection Agency (EPA) — as specified in EPA Regulation 40 CFR 26 (Protection of Human Subjects) and EPA Order 10000.17 A1 Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research (available from EPA's Program in Human Research Ethics (<http://www.epa.gov/osa/phre/index.htm>) — and the guidelines by the Department of Health and Human Services (DHHS) concerning protection of human participants (see *Instructions for Completing the Application*), on OMB form No. 0990-0263.

If HEI-Energy decides to fund a study involving human participants, the investigator needs to submit, before starting the study, a detailed protocol and documentation certifying that an appropriate Institutional Review Board (IRB), or similar institution, has reviewed and approved the proposed study in accordance with the DHHS regulations. The specific documentation that needs to be provided to HEI-Energy prior to starting the study is the following:

- The entire application to the IRB (including all supporting documentation submitted to the IRB, such as the study protocol, questionnaires, etc.);
- A signed statement of approval or exemption from the IRB;
- Approved informed consent document (if applicable) or a statement from the IRB that the investigator does not need to obtain informed consent.

According to EPA's rules, the EPA needs to review and approve all IRB-related documentation for all EPA-funded studies (including HEI-Energy studies) prior to the investigator starting the work. Therefore HEI-Energy will not sign a contract until it has received written approval from the EPA that the study's use of human participants complies with EPA regulations (40 CFR 26). The timely submission of the items listed above will avoid delays in the start of the study.

HEI-Energy also asks that the application to the IRB (including the informed consent document) be provided to HEI-Energy *at the time it is submitted to the IRB*. HEI-Energy may propose modifications to the informed consent document if it believes that the risks to the participants are not properly represented.

Applicants who are (a) utilizing data or samples from participants recruited for another study or (b) collecting additional samples from participants recruited for other studies, need to provide the IRB approval and informed consent document obtained for the original study and the IRB approval for the HEI-Energy study.

In addition, investigators will be asked to comply with HEI-Energy's **Special Quality Assurance (QA) procedures** (see also next paragraph).

QUALITY ASSURANCE AND QUALITY CONTROL

It is the policy of HEI-Energy to require that appropriate quality assurance (QA) and quality control (QC) procedures are in place for all approved research projects to ensure the scientific community, our sponsors, and the public that the data are acquired under defined conditions and are reliable and traceable. Please refer to HEI-Energy's **Quality Assurance Policies and Procedures** for detailed information about HEI-Energy's Quality Assurance procedures. This section provides a brief summary of investigator commitments related to quality assurance and control.

Quality Assurance Project Plan

Before the start of the study, investigators must complete a **Quality Assurance Project Plan (QAPP)**, which describes the detailed QA/QC procedures that will be implemented to ensure data quality and integrity. Investigators must submit the QAPP to HEI-Energy for review and approval before data any measurement, data gathering, or data generation activity may be started.

Quality Assurance Audits

In addition to the Quality Assurance Plan, HEI-Energy will select an outside qualified individual or team to serve as a quality assurance officer to aid in HEI-Energy's assessment of QA activities in the study. The external QA officer may conduct periodic audits during the course of the study to ascertain compliance with the study protocol and to examine records. The QA officer will also audit the final report of the study. The auditor reports to HEI-Energy's Director of Science. The audit reports are confidential and are not released to persons not directly involved in the management of the project.

The Principal Investigator, and their institution, have the primary responsibility for development and implementation of the procedures required by HEI-Energy for QA. In such cases, the applicant should indicate the period required for these activities and provide a separate budget.

PROGRESS REPORTS

The basic objective of the progress reports is to indicate what progress has been made and milestones achieved in the development of study procedures, which objectives have been completed, and what problems, if any, have been encountered. Progress reports are requested at 5 and 10 months during each contract year (except the final year, when the 10-month report is replaced by a *Final Report*, see below). Progress reports are reviewed by the Energy Research Committee and by HEI-Energy's scientific staff, who will provide feedback.

The five-month progress reports are used to check on general progress and provide an opportunity for timely feedback from the Energy Research Committee.

The ten-month report is a combined progress report and renewal application for the next year's funding. HEI-Energy's decision regarding renewal of the contract is based upon the information provided by the investigator in this report, and on an assessment by the HEI-Energy Research Committee that the study team is producing high quality research, is adhering to the Project Plan as originally proposed, and has made sufficient progress along the way, meeting the stated goals. Thus, this report should provide a detailed account of the results obtained during the funding period, as well as a work plan (including a revised Statement of Work), and a budget for the coming year. Any problems encountered or reasons for delay in meeting milestones should also be outlined and the investigator's plans for addressing these issues should any be described. If a study runs significantly behind schedule, a no-cost extension may be

negotiated. Any deviations from the original Project Plan or significant changes to the budget require approval from the Research Committee.

SITE VISITS

HEI-Energy may conduct site visits to the investigator's laboratory during the course of their studies. The site visit team consists of Energy Research Committee members, HEI-Energy scientific staff, and other external expert consultants as needed. The purpose of these visits is 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. The visits also provide an opportunity for an exchange of ideas between the investigator and other experts in the field.

HEI-ENERGY WORKSHOPS

HEI-Energy organizes webinars, workshops, and other forums to present research to other investigators funded by HEI-Energy or to a broader audience of interested stakeholders, including HEI-Energy sponsors, community members, policy-makers, and the general public.

Periodically, HEI-Energy also organizes workshops for investigators working on related research projects. Research Committee members and expert consultants may also participate in these meetings, which afford an opportunity for investigators doing related research to understand each other's research better and to explore opportunities for coordination of studies and collaboration. The cost for the PI attending the workshops will be paid by HEI-Energy and should not be included in the budget for the proposed study.

REPORTING INTERIM AND FINAL RESULTS

Investigators will be required to regularly engage with stakeholders. Investigators must be willing to work with HEI-Energy and other funded research teams before research commences to refine and harmonize their approach to performing analyses, reporting and interpreting interim and final results, and communicating interim and final results to interested stakeholders. HEI-Energy may also involve risk communication experts to guide communication plans.

FINAL REPORT

An important goal of HEI-Energy is to publish research reports of the highest scientific quality that will be of value to regulators, government officials, scientists, and the interested public. After the research has been completed, each HEI-Energy-funded Principal Investigator is required to prepare a comprehensive final report that describes the study and its findings. Because some of HEI-Energy's research projects are designed to provide information to be used in regulatory decisions, HEI-Energy places an emphasis on timeliness. Detailed instructions regarding the content of the final report and how to submit it are provided in the *Investigators' Guide: Preparing the Final Report*.

The HEI-Energy Review Committee, which has no role in either the selection of investigators for funding or the oversight of studies, evaluates the investigator's final report. The objectives of the HEI-Energy review process are to (1) evaluate the scientific quality and significance of the research, (2) point out the strengths and limitations of the study, (3) place the study into scientific and regulatory perspective, (4) identify future research opportunities, and (5) communicate all the findings (positive and negative) to the Institute's sponsors and the public.

Each final report additionally undergoes an external peer-reviewed by scientists with appropriate technical expertise, including a biostatistician. A compilation of the comments of the reviewers, together

with the Review Committee's initial review, is sent to the investigator, who has an opportunity to respond to these comments and, if necessary, to revise the report. At this stage, the Review Committee generally raises questions about methods, data, results and their interpretations, and conclusions drawn by the Principal Investigator. Occasionally, the Committee may request additional data analyses.

After revisions are received at HEI-Energy and the Review Committee has discussed them and approved the report, the Review Committee prepares a commentary and an HEI-Energy scientific editor edits the report. The Commentary also puts the research results into a broader context of related research, highlights its strengths and limitations, and discusses the interpretation, conclusions, and implications of the findings. The investigator is given an opportunity to respond to the commentary prior to publication and is asked to address the editor's queries. **The contractual obligation to prepare a comprehensive final report and to participate in the HEI-Energy review process distinguishes HEI-Energy from most other funding agencies.** Potential applicants should be aware of the effort associated with this responsibility and plan for it accordingly. HEI-Energy expects that the Principal Investigators and key members of the team will devote time during the last year of the study to the preparation and submission of the final report. Investigators should also be aware that report revisions and answering queries from HEI-Energy editing staff during the publication process will require additional time at a later date.

The HEI-Energy Research Reports, which consist of the investigator's final report and the Review Committee's commentary, are the principal means by which the Institute communicates results of its research and the evaluation and interpretation of those results. They are distributed to HEI-Energy's public and private sponsors, the scientific community, libraries that serve medical and scientific communities, and the general public. In addition, the HEI-Energy research reports are registered with the National Technical Information Services and the reports are indexed by bibliographic services such as PubMed.

Investigators should be prepared to submit, upon request from HEI-Energy, information underlying the final data analyses included in the report. Such information may include data sets that contain individual data as well as statistical code and output of statistical analyses with appropriate documentation. This information will be used internally at HEI-Energy and will be made available to the Review Committee to assist in their evaluation of the final report. Selected information may be included as appendices to the final report, in consultation with the investigator. Please note that this request is separate from the *Quality Assurance and Quality Control* requirements listed above.

POLICY ON DATA ACCESS

Providing access to data from studies is an important element in ensuring scientific credibility, especially for studies used in policy debates. HEI-Energy has developed a policy to provide access to data for studies that it has funded in a manner that facilitates the review and validation of the work. The policy also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the investigators who conducted the study.

The major responsibility for data management is delegated by HEI-Energy to the investigator. Where data, metadata, and code are stored and how they are made accessible varies, depending on the kind of data. If the investigator does not have a preference, HEI-Energy recommends the Harvard Dataverse, which is an open source web repository, designed to share, preserve, cite, explore, and analyze research data.

Various levels of security and access can also be implemented, but HEI-Energy's goal is to make data access as simple as possible, while respecting the rights of the investigators who generated the data and the confidentiality of any volunteers who may have participated in the study. For more details, please refer to HEI-Energy's **Policy on Data Management, Preservation, and Access**. The costs for data management should be included in the overall budget for the study.

PUBLICATIONS

HEI-Energy encourages investigators to publish results of research conducted under HEI-Energy funding in the open scientific literature. HEI-Energy retains a nonexclusive license to publish material from work funded by HEI-Energy; it is the responsibility of the investigator and his/her institution to notify other publishers of HEI-Energy's rights. A statement acknowledging HEI-Energy support and a disclaimer must appear in all publications resulting from work funded by HEI-Energy. **Please use the disclaimer language in your Research Agreement with HEI-Energy.**

Investigators are free to present material derived from work conducted with HEI-Energy funding in peer-reviewed scientific journals or at meetings of established scientific organizations. Investigators are required, however, to inform HEI-Energy about the dissemination of the findings; in particular, to send HEI-Energy a copy of all **manuscripts based on all or part of the HEI-Energy-funded work at the time they are submitted to a peer-reviewed journal, and final versions upon publication**. Similarly, investigators are also required to send **meeting abstracts before submission to allow time for review and the final version of the poster or presentation slides**. The Research Agreement also states that HEI-Energy “discourages the disclosure of the results of the work performed under this Agreement outside the scientific community until after such results have undergone scientific peer review.”