

# Investigator Commitments

HEI's research oversight and review processes are different from those at many other funding agencies as necessary to support our mission. Accordingly, HEI requires full transparency by sharing all results, not just those accepted for publication in peer-reviewed journals, and rigorous peer review and independent commentary on the research. Our rigorous process assures the continued trust in HEI as a provider of high-quality research for policy decisions. This page contains information about the scientific negotiation of project plans, the research agreement (contract), quality assurance program, progress reports, site visits, annual conference, final report, and publications. Applicants should read this page carefully to ensure that they understand the commitments in conducting studies with HEI funding before applying.

## **GOALS OF HEI OVERSIGHT**

HEI 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 policy agencies for technological and regulatory decisions. To accomplish those goals, HEI works in a cooperative fashion with investigators and keeps in close contact with them through such means as progress reports, workshops, and its Annual Conference. The progress reports are reviewed by the HEI Research Committee and staff and by outside experts, if deemed necessary by the Research Committee. In addition, HEI requires a comprehensive final report at the end of each study, which undergoes an in-depth review by the HEI Review Committee and additional experts. Depending on the study scope and methods, the study and the final report might also be subject to auditing by a third party (see below).

## **SCIENTIFIC NEGOTIATION OF PROJECT PLANS**

The Research Committee might request modifications in the project plan or budget before making a final funding recommendation to the HEI Board of Directors. For example, the Research Committee might request deletion of parts of the proposed project that are less relevant to HEI's objectives or overlap considerably with other studies or ask for changes in the range of exposure concentrations of pollutants to make them more representative of ambient conditions. This approach enables HEI to mold diverse investigator-designed studies into a more coherent research program and to generate data more relevant to regulatory needs. HEI 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; *no work can begin until the contract has been signed*. HEI's Research Agreement is a cost-reimbursement contract rather than a grant. Investigators should be aware that scientific and administrative contract negotiations can sometimes take several months, which can precipitate a change in the start date. Before a contract can be finalized, HEI requires the following:

- ✓ Revised budgets, project plans, or other appropriate application materials that reflect substantive changes in personnel, scope of work, or budget from the original application.
- ✓ A preliminary quality assurance (QA) and quality control (QC) plan; see Quality Assurance Section below and HEI [QA/QC Procedures](#).
- ✓ Additional materials for studies that involve human participants (see section below).

The contract contains a Statement of Work (a brief description of work to be performed in each contract year), the original or amended proposal, 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 can be amended to allow changes in the Statement of Work upon written agreement between the investigator's institution and HEI.

Contracts are usually issued for one year, although HEI 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 will be posted on the [HEI website](#).

*Investigators cannot begin work or incur any study costs before the contract has been signed, a QA/QC plan has been approved by the HEI Research Committee, and written approval or exemption by an Institutional Review Board or equivalent ethics board has been obtained for applicable studies (see below), unless explicit written authorization is provided in advance by HEI's Director of Finance and Administration.*

## STUDIES INVOLVING HUMAN PARTICIPANTS

As mentioned in the section on [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 the guidelines by the Department of Health and Human Services (DHSS) concerning protection of human participants (see *Instructions for Completing the Application*), on OMB form No. 0990-0263 (page F-11 of HEI application forms).

If HEI decides to fund a study that involves human participants, the investigator needs to submit, before starting the study, a detailed protocol and documentation certifying that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed study in accordance with the DHHS

regulations. The specific documentation that needs to be provided to HEI before 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 and questionnaires.
- ✓ 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, EPA needs to review and approve all IRB-related documentation for all EPA-funded studies (including HEI studies) before the investigator starts the work. Therefore, HEI will not sign a contract until it has received written approval from 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 also asks that the application to the IRB (including the informed consent document) be provided to HEI at the time it is submitted to the IRB. HEI might propose modifications to the informed consent document if it believes that the risks to the participants are not properly represented.

Applicants who are (a) using 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 study.

In addition, investigators will be asked to comply with HEI's [Special Quality Assurance procedures](#) (see also next paragraph).

## QUALITY ASSURANCE AND QUALITY CONTROL

It is the policy of HEI 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. There are two tiers of QA/QC procedures that HEI applies to all funded studies: general QA/QC procedures for all HEI funded studies and special QA/QC procedures for studies of regulatory significance or that involve human participants. Please refer to the [QA/QC Procedures](#) page.

Under the **General QA/QC procedures (Part I)**, HEI requires each funded investigator to provide a QA Plan that describes the overall QA/QC procedures that will be implemented to ensure data quality and integrity. The Plan should include the following six components: (1) the research protocol, (2) a list of standard operating procedures and data protocols, (3) quality control procedures for data collection, (4) data processing, linkage, and analysis procedures, (5) data and records management, and (6) a list of qualified personnel. A preliminary QA Plan should be developed and submitted to HEI before the contract is signed. The HEI Research Committee will review and approve and QA Plan, after which the study can start.

**Special QA/QC procedures (Part II)** pertain to approved research projects that could produce data of regulatory significance and include all studies that involve human participants. For these studies, HEI will select an outside qualified individual or team to serve as a QA officer to aid in HEI's assessment of QA activities in the study. The external QA officer may conduct periodic audits to ascertain compliance with the study protocol and to examine records. The QA officer will also audit the final report of the study. They report to HEI's Director of Science. The audit reports are confidential and are not released to people 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 for QA.

[Form to submit a QA plan](#) (Word)

## **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).

The 10-month report is a combined progress report and renewal application for the next year's funding. HEI's decision regarding renewal of the contract is based on the information provided by the investigator in this report and on an assessment by the HEI 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 to meet the stated goals. Thus, the report should provide a detailed account of the results obtained during the funding period, 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 the issues should be described. If a study runs substantially behind schedule, a no-cost extension (typically no more than 2-3 months) can be negotiated. Any deviations from the original project plan or substantive changes to the budget require approval from the Research Committee. Progress reports are reviewed by the Research Committee and by HEI's scientific staff.

Ten-month progress reports for studies funded under the Walter A. Rosenblith New Investigator Award should be accompanied by a letter from the mentors signing off on the progress report and reporting on the communications with the awardee and other mentoring that has taken place during the past year.

[Progress Report Template](#)

## **SITE VISITS**

HEI might conduct in-person or virtual informational site visits to the laboratories of its funded investigators during their studies. The site visit team consists of members of the HEI Research Committee, HEI scientific staff, and other experts. The purpose of the visits is to evaluate the status of

the project, to provide the investigator with expert technical advice, and to provide an opportunity for an exchange of ideas between the investigator and other experts in the field.

## **HEI ANNUAL CONFERENCE AND OTHER MEETINGS**

Each year, HEI holds a conference that all Principal Investigators are expected to attend. The [HEI Annual Conference](#) provides an opportunity for HEI's sponsors to learn more about HEI studies, for HEI to receive feedback on its research program, and for informal interactions among investigators, Research and Review Committee members, sponsor representatives, and the HEI staff. Each investigator is asked to submit an abstract and poster. Abstracts and posters are made available on the HEI website in conjunction with the Annual Conference. In addition to discussion of HEI program areas, the Annual Conference generally includes special symposia on broader issues of current interest. Periodically, small workshops are organized for investigators working on projects in a particular research area. These meetings offer an opportunity for investigators doing related research to understand each other's research better and might provide opportunities for coordination of studies or collaboration among investigators. In addition, critical gaps in HEI's program or ideas for new research might be identified. The cost for the Principal Investigator to attend the conference will be paid by HEI and should not be included in the budget for the proposed study.

## **FINAL REPORT**

An important goal of HEI 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-funded Principal Investigator is required to prepare a comprehensive final report that describes the study and its findings. Because some of HEI's research projects are designed to provide information to be used in regulatory decisions, HEI places an emphasis on timeliness. Templates and guidance for preparing the final report are [located here](#). Potential applicants should be aware of the effort associated with this responsibility and plan for it accordingly.

## **POLICY ON DATA ACCESS**

Providing access to data from studies of the health effects of air pollution is an important element in ensuring scientific credibility, especially for studies used in policy debates. HEI 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 participated in the study and respects the intellectual interests of the investigators who conducted the study. Please refer to the [Data Access and Transparency](#) page.

## **PUBLICATIONS**

HEI encourages investigators to publish results of research conducted under HEI funding in the open scientific literature. HEI retains a nonexclusive license to publish material from work funded by HEI; it is the responsibility of the investigator and their institution to notify other publishers of HEI's rights. A statement acknowledging HEI support and a disclaimer must appear in all publications resulting from work funded by HEI. **Please use the disclaimer language in Article 16 of your Research Agreement with HEI.**

Investigators are free to present material derived from work conducted with HEI funding in peer-reviewed scientific journals or at meetings of scientific organizations. Investigators are required, however, to inform HEI about the dissemination of the findings and send HEI a copy of all manuscripts based on all or part of the HEI-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 at the time of submission and the final version of the poster or presentation slides. Article 16 also states that HEI "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."

## **CONFLICT OF INTEREST**

HEI requires investigators to disclose any potential conflicts of interest. Investigators should report financial relationships with entities in the exposure science or environmental health areas that could influence or be perceived to influence the research described in the final report. For more information, see the HEI [Conflict of Interest Policies](#).

This document contains the text on this webpage:  
<https://www.healtheffects.org/research/investigators/commitments>

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