

INSTRUCTIONS FOR COMPLETING THE APPLICATION

Contents

General Information.....	2
Application Process and Deadlines.....	2
Eligibility	2
Preliminary Application.....	2
Estimated Budget and Schedule.....	2
Project Plan	2
Stakeholder Engagement Plan	3
Qualification of Investigators.....	3
Biosketches	3
Full Application	3
General Information.....	3
Abstract of the Project Plan (Form F-3).....	4
Budget (Forms F-4a through F-5b).....	4
Project Plan (Form F-6)	7
Decision Framework to Guide Data Collection and Interpretation of Findings (Form F-7)	8
Stakeholder and Community Engagement Plan (Form F-8).....	9
Other Support (Form F-9).....	10
Resources and Environment (Form F-10).....	10
Biographical Sketches (Form F-11).....	10
Human Participants (Form F-12).....	10
Human Subjects, Derived Materials, or Data (Form F-13).....	12
Letters of Support (Form F-14).....	12
Personal Data (Form F-15 — Optional)	12
Conflicts of Interest Disclosure (Form F-16).....	12

GENERAL INFORMATION¹

Application Process and Deadlines

General Information

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

- Investigators should initially submit a **Preliminary Application** by September 24, 2020, which will be reviewed by the Energy Research Committee. A limited number of investigators will be invited to submit a full application. Applicants will be informed whether or not to submit a full application by early November 2020.
- Invited investigators should then submit a **Full Application** by February 1, 2021, which will be reviewed by a Special Review Panel before consideration by the Energy Research Committee.

All applications should be typed single-spaced, within the margin limitations indicated on the forms (1 inch minimum) and using a minimum font size of 11 pt. All forms are available for download at <https://hei-energy.org/funding-opportunities/rfa/e20-1-e20-2>. The application should be submitted as a single file in PDF format with appropriate bookmarks and title for each section of the application.

Questions about applications should be directed to Anna Rosofsky (arosofsky@healtheffects.org).

Submission

Preliminary and full applications should be submitted to Janet McGovern electronically at energyfunding@healtheffects.org. HEI-Energy will acknowledge receipt of preliminary applications.

Eligibility

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

PRELIMINARY APPLICATION

Preliminary applications provide a brief description of the proposed research and investigative team. Applications must abide by the HEI-Energy Preliminary Application Form with an estimated total budget, project plan, stakeholder engagement plan, qualification of investigators, and biographical sketches.

Estimated Budget and Schedule

The application should include an estimate of the time and approximate estimate of funds required to complete the study. Detailed budget pages are not required at this time.

Project Plan

The project plan should include a brief description of the following: scientific background and rationale, hypothesis and study aims, any preliminary or relevant data from previous studies, study design and

¹ Any contract awarded under this Request for Applications is expected to be funded in part by a contract from the U.S. Environmental Protection Agency. This award process will be subject to regulations contained in 40 CFR Subchapter B, and particularly Part 30 thereof. Neither the United States nor the U.S. Environmental Protection Agency is nor will be a party to this Request for Applications or to any resulting agreement.

HEI-Energy and its funded institutions are subject to the Office of Management and Budget and EPA accounting regulations. Please provide a DUNS number for your institution.

methods for data collection, proposed statistical analyses, an overarching explanation of the project's quality assurance and management plan, and anticipated results of the research. The project plan should include a discussion of how the proposed research satisfies the criteria listed in the RFA under "Evaluation Process for Full Applications."

Stakeholder Engagement Plan

HEI-Energy will host stakeholder workshops in study areas before commencement of research and on an annual basis while research is ongoing. However, research teams will play a critical role in stakeholder engagement before, during, and after the research program. The Stakeholder Engagement section should include a brief (< 200 words) description of the plan for engaging with community members and community groups in areas proposed for study as well as other stakeholders (e.g., oil and gas industry, local government, and academics) with interest in the proposed research. Explain the general approach to engagement with stakeholders and integration of their input into research.

Qualification of Investigators

Explain how your team is uniquely positioned to deliver results and why you are the best choice to meet the aims put forth in the RFA. The preliminary application should specify the expertise and experience of anticipated collaborators and briefly describe how their expertise would contribute to designing and conducting the study, analyzing the data, and interpreting study findings. Be sure to highlight experience with relevant study design and data collection methods (e.g., field work) and community engagement in study locations. Where relevant, a list of special equipment and facilities that would be available for the project should be included. For research proposed in multiple regions, describe how research will be coordinated across study locations.

Biosketches

Brief biosketches (maximum 2 pages per person) of the principal investigator and key co-investigator(s) should be provided using HEI-Energy form F-11 or similar 2-page format.

FULL APPLICATION

General Information

Applications must be submitted on the HEI-Energy Application for Research Agreement (forms F-1 to F-13). A complete full application consists of:

- Forms F-1 through F-3: Overall project plan (required)
- Forms F-4a through F-5b: Project budget (required)
- Form F-6: Project plan in detail (required, maximum 15 pages)
- Form F-7: Decision framework (required, 2 pages)
- Form F-8: Stakeholder and Community Engagement Plan (required, 2 pages)
- Form F-9: Current and pending grants from which the investigators are currently drawing support (required)
- Form F-10: Resources and Environment (required)
- Form F-11: Biographical sketches for all professional personnel and consultants involved in the project (required, 2 pages per individual)
- Form F-12: Human Participants (required where applicable)
- Form F-13: Protection of Human Subjects (required where applicable)
- Form F-14: Letters of Support (required where applicable)

- Form F-15: Personal data on the principal investigator (optional)
- Form F-16: Conflicts of Interest
- Application completion checklist

Abstract of the Project Plan (Form F-3)

Concisely describe the application's specific aims, methodology, and long-term objectives, referring to the scientific disciplines involved and the relationship of the project to the objectives of HEI-Energy and the Request for Applications. The abstract should be self-contained so that it can serve as a succinct and accurate description of the application when separated from it.

The Project Title should not exceed 20 words and the Abstract should not exceed 500 words.

Budget (Forms F-4a through F-5b)

Overview

Provide adequate data and analysis to assure HEI-Energy that the proposed costs are necessary and reasonable and that adequate accounting procedures will be used. Budgets should be prepared assuming a project start date of July 1, 2021.

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

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

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

The total budget should include funds and an appropriate percent effort from key personnel for writing the final report in the final year of the study. Investigators should also be aware that additional time effort is expected at a later time to address requests for revisions and answering editorial queries. Please refer to the *Final Report* section in *HEI-Energy Investigator Commitments* (see separate document) for details.

Personnel

List the names and positions of all applicant organization personnel involved in the project, both professional and nonprofessional, whether or not salaries are requested. Estimate the percentage of time or effort, or hours per week, on the project for professional personnel in relation to the total professional activity commitment to the applicant organization; estimate the hours per week on the project for nonprofessional personnel. List the dollar amounts separately for each individual for salary and fringe benefits. Fringe benefits may be requested to the extent that they are treated consistently by the applying organization as a direct cost to all sponsoring agencies.

The amount to be reimbursed to each individual, when added to their compensation for all other full-time duties, should not exceed the individual's base salary. In computing estimated salary changes, an individual's base salary represents the total authorized annual compensation that an applicant organization would be prepared to pay for a specific work period whether an individual's time is spent on sponsored

research, teaching, or other activities. The base salary for the purposes of computing charges to an HEI-Energy Research Agreement excludes income that an individual may be permitted to earn outside of full-time duties to the applicant organization.

Where appropriate, indicate whether the amounts requested for the principal investigator and other professional personnel are for summer salaries or academic-year salaries and indicate the formulas for calculating summer salaries.

Indicate whether current rates or escalated rates are used. If escalation is included, state the degree (percent) and methodology, e.g., annual flat rate applied to base rate as of a specific date or a mid-point rate for the period of performance.

HEI-Energy requires the involvement of a (bio)statistician in the study design, selecting appropriate statistical approaches, and the final data analysis and interpretation. Statisticians can be included under the main study personnel or as consultants. If the investigator's institution provides core statistical services, this should be indicated; in this case, a particular statistician should be identified by name. Exemption from this requirement can be obtained only if the Principal Investigators or other key personnel have appropriate expertise in this area, evidence of which should be submitted as part of the application. The statistician's involvement should be evident in the application, for example by including a letter from the statistician indicating that they have read the application and approve the study design and statistical approaches. (See also *Additional Submissions* below).

Consultant Costs

Consultant service should be explained by indicating the specific area in which such service is to be used. Identify the contemplated consultants. State the number of days of such services estimated to be required and the consultant's quoted rate per day, and indicate the number of hours per day in which work will be performed. The maximum consultant rate is \$ 655.38/8-hr day. HEI-Energy's participation in consultant costs is subject to limits set by federal regulations. (See also *Additional Submissions* below).

Supplies and Other Expenses

All supplies and other expenses should be itemized in sufficient detail to allow reviewers to understand the major categories of expenditures (i.e., glassware, media, chemicals, animal purchase and housing, as well as publication costs, page charges, and books, listed by category and unit cost). Itemize and justify such items as patient compensation, travel, per diem costs, rentals, leases, and computer costs. Unusually expensive items for special processes should be separately identified by quantity and price and the use or application thoroughly explained in the project plan. Each individual expense item must be categorized as supplies or other expenses according to the practices of the accounting office of your institution. Items that cost more than \$5,000 should be listed under equipment (see below).

The costs of construction per se are not permissible charges. If the costs of essential alterations of facilities, including repairs, painting, removal or installation of partitions, shielding, or air conditioning, are requested, itemize them by category and justify them fully. When applicable, indicate the square footage involved, giving the basis for the costs, such as an architect's or applicant's detailed estimate. When possible, submit a line drawing of the alterations being proposed.

Travel Expenses

Limit travel to one scientific meeting per year. If travel is required for other purposes, such as meetings with collaborators, indicate the estimated number of trips, destination, reason for travel, and cost. Identify and support any other special transportation costs attributable to the performance of this project, including attendance at workshops in each study region at the outset of the research program, and before field work commences, to present their research plan..

Indirect Costs

Indirect costs are limited to a maximum of 30% of direct costs excluding equipment charges and subcontracts. Indirect costs cannot be greater than the government-negotiated rate for your institution. Expenses normally included in the calculation of the indirect cost rate may not be itemized as direct expenses. A copy of your institution's most recent approved indirect cost rate should be sent to HEI-Energy once the study has been approved for funding (it is not needed with the application).

The HEI-Energy Board of Directors has approved a very limited exception to this cap on indirect costs for organizations that can meet both of the following conditions: (1) the research institution provides a unique capability for a project essential to HEI-Energy's mission, and (2) the institution is prohibited by the U.S. Government from accepting less than full cost recovery.

Equipment

Provide an itemization and justification of all equipment to be purchased or fabricated for use in this study. Please note that HEI-Energy reimburses institutions only for those equipment items explicitly listed in the Approved Budget or subsequently authorized in writing by HEI-Energy's Director or Director of Finance & Administration. The equipment budget is not subject to indirect cost charges. Equipment valued less than \$5,000 should be listed under supplies.

Subcontracts

Itemize and enter a total for these costs. Describe and justify all appropriate costs for services purchased for, or associated with, third parties, including applicable indirect costs. These costs may include, but are not necessarily limited to, consortium agreements or formalized collaborative agreements. Indirect costs for subcontracts are also subject to HEI-Energy's 30% cap (see above). Develop separate budgets for the initial and future budget periods for each organization involved in consortium arrangements or formalized collaborative agreements, and submit them using the appropriate budget form (F-4b and F-5b). The principal investigator's institution may charge Indirect costs to the first \$25,000 of each subcontract.

Budget Justification

a. Personnel and Consultants

For the total budget and subcontracts, briefly describe the specific functions of the personnel and consultants. For each year, justify any cost for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and contractual or third party costs. For future years, justify any significant increases in any category. If a recurring annual increase in personnel costs is anticipated, give percentage. Note that an Institutional Cost Rate Agreement should be submitted once the project has been approved for funding.

b. Community and Stakeholder Engagement

Describe the costs associated with community and stakeholder engagement. Investigators must allocate 5% of their budget to community and stakeholder engagement activities, including developing partnerships, holding community and stakeholder meetings, developing print and electronic materials to communicate information relevant to study activities and results. HEI-Energy will cover travel and logistical costs for investigator workshops and stakeholder workshops hosted by HEI-Energy.

c. Preparation of Quality Assurance Project Plan

Before research commences, and in the first year of funding, Investigators must prepare a Quality Assurance Project Plan. All costs associated with preparation of the Plan should be indicated here.

d. Data Accessibility

Specify the costs associated with retaining the data and making it publicly accessible in accordance with HEI-Energy's *Policy on Data Management, Preservation and Access*.

Project Plan (Form F-6)

The Project Plan should include all the sections listed below. Include sufficient information in the Project Plan and in any appendix to facilitate an effective review. Be specific and informative and avoid redundancies. Sections A, B, and C together should total no more than three single-spaced pages. HEI-Energy reserves the right not to consider proposals that exceed this limit. Appendices may be provided as supplementary information, but review will be based mainly on the information provided in the Project Plan. Section D should be concise but adequately detailed to permit critical evaluation. Sections D, E, and F combined should not exceed 12 pages (excluding references). Please use an 11-point font size or larger and 1-inch margins.

A. Specific Objectives

State concisely and realistically what the research described in this application is intended to accomplish and what hypothesis is to be tested.

B. Background and Significance

Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to the stated objectives of HEI-Energy and explain the regulatory significance.

C. Related Previous Studies

Provide an account of, and references to, the principal investigator's previous studies pertinent to the application and/or any other information, including preliminary findings, that will help to establish the experience and competency of the investigator to pursue the proposed project. The appendix can be used for published references or details of available pilot studies.

D. Experimental Plan and Methods

Discuss in detail the experimental design and the procedures to be used to accomplish the specific aims of the project.

Define your study sample and explain the rationale for choosing it. If the study involves human participants, describe how they will be selected, and the informed consent procedure. (See Additional Submissions below).

Provide sufficient details of the experimental design and study protocol so that it can be understood clearly by the reviewers. Applicants should provide details of exposure systems for specific agents (and the rationale for their selection), randomization procedures, methods used for any blinding of observations, and the proposed number of observations. Describe any new methodology and its advantage over existing methodologies.

Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

E. Quality Assurance and Quality Control

Describe the procedures to be used to ensure that the quality of the data is adequate in view of the objectives of the study [see Quality Assurance and Quality Control (QA/QC) Procedures Document].

Detailed QA/QC information should not be submitted with the original application but will be requested for successfully funded studies.

F. Statistical Design and Analysis Plans

Provide a description of the statistical methods to be used for analysis and interpretation of the data. Describe the proposed statistical procedures with sufficient detail to allow evaluation by a (bio)statistical reviewer. Include calculation of statistical power, and a justification of the proposed numbers of animals/participants/samples. Please note that in addition to reviews by experts in the subject matter, HEI-Energy often asks statisticians to review the statistical design of studies.

G. Milestones and Timeline

Please include a list of milestones to be met during the project, with a timeline. Please use this template and fill in the cells to indicate when a specific aim or task will be ongoing and completed.

Milestone Chart					
	Year 1				(etc.)
	Q1	Q2	Q3	Q4	(etc.)
Specific Aim 1: (add text)					
Task 1: (add task)					
Task 2: (add task)					
(etc.)					

H. Literature Cited

References in the text should consist of author and year. Provide complete citations in alphabetical order at the end of the Project Plan.

Decision Framework to Guide Data Collection and Interpretation of Findings (Form F-7)

Investigators must include a Decision Framework in their proposals that addresses the topics described below, recognizing that some detail cannot be provided at the proposal phase but will need to be provided once final study designs have been established. HEI-Energy expects investigators to specify their Decision Framework before data collection begins.

A. Data Collection and Analysis.

The Decision Framework should specify how the investigators will sequence data collection and analysis in a manner that maintains focus on important potential exposures, while ensuring the efficient use of resources. For example, investigators might choose to study a longer list of chemical analytes or a broader geographic area in an early phase of research and define and use specific criteria for reducing the number of chemical analytes or the geographic scope. Investigators should describe how interim analyses of collected data will inform later phases of data collection (i.e., building on the previous phase of data collection). Investigators should integrate this Framework into their quality assurance plan throughout all phases of research.

B. Scientific Interpretation of Results.

The investigators should include in their Decision Framework an approach for integrating their study findings to describe the type, magnitude, and likely sources of observed exposures associated with UOGD processes. This section of the Framework should also address the representativeness and generalizability of the integrated study findings, the relevance of the observed exposures under future conditions and, where possible, the potential effect of source or exposure mitigation measures. Where feasible, the

Framework should incorporate results interpretation in light of the fraction of UOGD operations or locations represented by study results. In addition, HEI-Energy expects investigators to include in their Decision Framework specifications for determining the utility of continued exposure research or future health research based on their findings.

C. Health Risk-Based Interpretation of Results for Communities in Study Locations.

In the Decision Framework, HEI-Energy expects investigators to specify their plan for interpreting and communicating interim and final results in the context of health risk for communities living in their study locations. Investigators should integrate this aspect of the Framework into their broader Stakeholder Engagement Plan and cross-reference the Stakeholder Engagement Plan where applicable.

Stakeholder and Community Engagement Plan (Form F-8)

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

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

The outline should provide a plan describing:

A. Research team member expertise.

Describe the team members with the expertise and responsibility to implement the plan, including previous experience with stakeholder engagement in environmental health research.

B. Anticipated stakeholder groups

Describe the stakeholder and community groups that the stakeholder plan will target and the approach that will be used to identify interested community members in the study area and other stakeholders.

C. Approach to engage stakeholder groups and foster relationships

Describe the strategies to optimize constructive stakeholder engagement and to foster relationships among the research team, community members, industry representatives, government officials, and other local stakeholders during research.

D. Approach for communication of study designs and results

Describe the approach to ensuring that research translation and communication of study designs and results occurs through culturally appropriate means, and the key intervals during the research program when engagement will occur. Examples include creation of a website, fliers, announcements in local media outlets, and webinars. Research that involves communities spread across large geographic areas might require other forms of stakeholder engagement (e.g., webinars) to encourage extensive participation.

E. Expected outcomes

Describe the expected outcomes from implementation of the Stakeholder Engagement Plan, including plans to respond to stakeholder input regarding study design, communication, and use of results for decision-making.

Other Support (Form F-9)

Describe current and pending grants or contracts from which each of the investigators proposed for this project are now drawing or anticipate drawing support. Identify project by title, agency, or organization supporting such work, the total level of financial support given for the project, the percentage of time (or calendar months) spent on each project, and the (projected) start and end dates. Briefly describe the contents of each. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, justify and delineate the nature and extent of the scientific and budgetary overlaps or boundaries.

Resources and Environment (Form F-10)

A. Facilities

Describe all the facilities to be used and, in the space provided, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Using continuation pages if necessary, include a description of the nature of any collaboration with other organizations and provide further information in the “Research Plan.”

B. Major Equipment

List the most important equipment items available for this project, noting the location, and pertinent capabilities of each.

C. Sponsor Participation

If “YES” has been marked under sponsor participation (i.e. any of the organizations funding HEI-Energy), please explain on a separate page the nature of sponsor participation. Identify and explain the role of any individual employed by U.S. EPA or industry sponsors of HEI-Energy who is involved with any aspect of the proposed study. Also, list any resources provided by sponsors, including equipment, and facilities. Please note that employees of organizations funding HEI-Energy cannot receive funds from HEI-Energy for salary or any other costs.

Biographical Sketches (Form F-11)

Provide information on the education and research and/or professional experience for professional personnel and consultants beginning with the Principal Investigator. Do not exceed 2 pages per individual.

Human Participants (Form F-12)

Safeguarding the rights and welfare of human participants in projects supported by EPA grants is the responsibility of the institution, which receives or is accountable to EPA for the funds awarded for the support of the project. The EPA regulations require applicant institutions to comply with the Department of Health and Human Services (DHHS) guidelines for human participants as well as additional requirements specified by the EPA. HEI-Energy is responsible for ensuring that these guidelines are followed by all institutions and investigators receiving HEI-Energy funds.

The institution must submit to HEI-Energy, for review, approval, and official acceptance, a written assurance of its compliance with guidelines established by the U.S. Department of Health and Human Services concerning protection of human participants. However, institutions that have submitted and have had accepted general assurance to DHHS under these guidelines will be considered as being in compliance with this requirement (as documented by form F-12). The DHHS's regulation, 45 CFR 46, is available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892, or from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20420, USA (or see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). Institutions outside the U.S. that have not obtained assurance of compliance to DHHS will need to provide assurance of compliance to the World Health Organization/Council for International Organizations of Medical Sciences (WHO/CIOMS), national agencies, or United Nations agencies.

If the application involves human participants, the application should include the following information on Form F-13 (additional details are found in the *Policy for Human Subjects Research*):

- Identify the sources of the potential participants, derived materials, or data. Describe the characteristics of the participant population, such as their anticipated number, age, gender, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for research involving fetuses, in vitro fertilization, pregnant women, children, institutionalized mentally disabled participants, prisoners, or other participants, especially those whose ability to give voluntary informed consent may be in question.
- Describe the recruitment and consent procedures to be followed, including the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective participants, and the methods of documenting consent. Include the consent form to be used.
- Describe potential risks to the participants — physical, psychological, social, legal, or other — and assess their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used.
- Describe the procedures for protecting against or minimizing potential risks and include an assessment of their likely effectiveness. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing medical treatment if needed.
- Describe and assess the potential benefits to be gained by the participants, as well as the benefits that may accrue to society in general as a result of the planned work.
- Discuss the risks in relation to the anticipated benefits to the participant and to society.

If HEI-Energy decides to fund a study involving human participants, the investigator will be asked to submit a detailed protocol before starting the study and to comply with HEI-Energy's special QA/QC procedures (see *Investigator Commitments* and *QA/QC Procedures*). Approval of the study by the Institutional Review Board (IRB) at the investigator's institution is required before starting a study with human participants. In addition, HEI-Energy will need to obtain approval from EPA before signing the contract, as described under *Investigator Commitments*. Documentation submitted to HEI-Energy should include (1) the complete application to the IRB; (2) consent forms, if applicable; and (3) a signed letter from the IRB indicating that the study has been approved or exempted.

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.

Human Subjects, Derived Materials, or Data (Form F-13)

If Item 6 on the Title Page (Form F-1) of the application has been marked “YES,” submit OMB form No. 0990-0263 (page F-12 of HEI-Energy application forms).

Letters of Support (Form F-14)

Consultant(s)

Consultant arrangements and proposed collaborations with investigators at other institutions must be confirmed in writing. Attach appropriate letters from each individual, confirming their role in the project.

Statistician(s)

The assigned (bio)statistician needs to provide written confirmation that they (1) have reviewed and approved the study design and statistical approaches, and (2) will be actively involved in data analysis and interpretation.

Other Letters of Support

Please provide letters of support where applicable, indicating the type of support the collaborators will provide. Examples include:

- Access to facilities
- Data sharing
- Collaboration with communities or community groups

Personal Data (Form F-15 — Optional)

HEI-Energy has a continuing commitment to monitoring the operation of its review and award process to detect, and deal appropriately with, perceived or suspected inequities with respect to age, ethnicity, race, or gender of the proposed principal investigator. To provide HEI-Energy with the information needed to fulfill this commitment, we request that each applicant complete the optional personal data form. Upon receipt at the HEI-Energy office, this form will be separated from the application and used only for internal HEI-Energy monitoring procedures. If you do not wish to provide this information, or do not complete the form, it will in no way affect consideration of your application.

Conflicts of Interest Disclosure (Form F-16)

In addition to information on sources of Other Support (Form F-9), HEI-Energy requires investigators to disclose any personal 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 proposed research. Please report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the past 36 months greater than \$3,000. Disclose any personal fees (monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony) and non-financial support (for example reagents or equipment, travel costs, etc.). Report also any patents, whether planned, pending or issued, broadly relevant to the work. Report any other relationships or activities, including investment interests (stocks, bonds, and other financial instruments and investments, including partnerships).