This document includes information for preparing Preliminary Applications and Full Applications in response to active HEI RFAs.

A list of our currently active RFAs is available under Funding Opportunities.

All necessary application forms are available under Instructions and Forms.

Please also see our FAQ page for other information about applying to HEI.

All applications should be submitted by the deadline stated in the specific RFA to funding@healtheffects.org. File size limit is 20 MB. HEI will confirm receipt of the application.

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PART 1: PRELIMINARY APPLICATIONS

Applicants should use the HEI Preliminary Application Form that requests the following information: title, plain language summary, project description including the study aims, design and methods, and anticipated results, project plan, community engagement plan where applicable, qualifications of investigators, and biographical sketches.

The preliminary application must not exceed 5 pages (11-point font size and 1-inch margins, single-spaced), including the cover material, but excluding references, biosketches, and supporting letters, where applicable. Longer applications will be rejected. The application forms should be converted to PDF format before submitting.

PLAIN LANGUAGE SUMMARY

The plain language summary indicating the purpose of the study, population(s) to be studied, and datasets and approaches to be used (max 150 words).

STUDY DESCRIPTION

General

The study description should include each of the following: scientific background and rationale, hypothesis and study aims, preliminary or relevant data from previous studies, study design and methods, statistical analyses, and anticipated results. The project plan should discuss the novelty of the proposed approach and how the study addresses the RFA objectives and satisfies the criteria listed in the RFA under “Evaluation Process for Full Applications.”

Community Engagement

Proposals where community engagement is indicated should describe community stakeholders that the investigators plan to engage, the general approach to engagement, and integration of community stakeholders into the proposed research (an additional ½ page). Specify how the community engagement will benefit the research and community members. Applications that require high levels of community engagement, such as sampling within a community or community partnerships, require a Letter of Collaboration to be sent with the Preliminary Application.

Qualifications of the Investigator(s)

Explain how the team is uniquely positioned to deliver results and why the team is the best choice and has the resources to meet the objectives 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. Highlight experience with relevant study design and data collection methods (e.g., field work) and community engagement.

BIOGRAPHICAL SKETCH

Include biographical sketches of the principal investigator and key co-investigators. Applicants can use the HEI Biosketch form or another format as long as each biosketch is no longer than two pages.

SUPPORTING LETTERS

Include letters of support as indicated in the RFA at the preliminary application stage.

ROSENBLITH APPLICATIONS, ONLY

Rosenblith Award applicants should include only their own biosketch. Co-investigators are not allowed under the Rosenblith RFA, but junior personnel are allowed. Mentors should be listed on the form. A cover letter, mentor biosketches, and letters of recommendation are NOT needed at this stage.
GENERAL INFORMATION

Full applications (by invitation only) must be submitted on the HEI Application for Research Agreement (Forms F-1 to F-12). Applications should be typed single-spaced, within the margin limitations indicated on the forms (1-inch minimum), and use a minimum font size of 11 pt.

HEI 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.

ROSENBLITH APPLICATIONS ONLY

COVER LETTER

The cover letter describes the applicant’s interest in the award and how this project fits with their career goals, including information concerning their long-term career plans and how the HEI Award would contribute to these plans.

TWO LETTERS OF REFERENCE

The two letters of reference should be from well-established scientists familiar with the candidate’s professional capabilities but who are not directly involved in the proposed project. See the RFA for details.

FACE PAGE (FORM F-1)

This form must be signed and dated by a legal representative and the study principal investigator.

TABLE OF CONTENTS (FORM F-2)

Finalize the table of contents and add page numbers once the application has been completed.

ABSTRACT OF THE PROJECT PLAN (FORM F-3)

Concisely describe the project’s specific aims, methodology, and long-term objectives of the research. Refer to the scientific disciplines involved and the relationship of the project to the objectives of HEI 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. Do not exceed one page.

BUDGET (FORMS F-4 AND F-5)

Cost or Pricing Data: Provide adequate data and analysis to assure HEI that the proposed costs are necessary and reasonable and that adequate accounting procedures will be used. Please refer to the RFA for specific instructions on projected start date and budget caps.

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 and effort is expected at a later time to address requests for revisions and answer editorial queries. Please refer to the Final Report section in HEI Investigator Commitments 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. Note that under the Walter A. Rosenblith New Investigator Award, senior personnel and mentors cannot be included for salary support. 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, and estimate the hours per week on the project for nonprofessional personnel. List the dollar amounts separately for each individual for salary and fringe

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1 Any contract awarded under this Request for Applications is expected to be funded in part by a grant 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

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 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 requires the involvement of a (bio)statistician in the study design, selection of 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 $650/8-hr day. HEI’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. Do not include the travel to the HEI Annual Conference within the budget because HEI will cover these costs directly. 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. HEI pays for foreign travel only if it is approved in advance of the trip.

INDIRECT COSTS

Indirect costs are limited to a maximum of 30% of direct costs excluding equipment charges and subcontracts. In addition, indirect costs cannot be greater than the government-negotiated rate for your institution (e.g., if the approved rate is 25%). 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 will be requested if your study is selected for funding.

The HEI 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’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 reimburses institutions only for those equipment items explicitly listed in the Approved Budget or subsequently authorized in writing by HEI's Director of Science or Director of Finance & Administration. The equipment budget is not subject to indirect cost charges.

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’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 Engagement. Describe the costs associated with community engagement, including developing partnerships, holding community and stakeholder meetings, and developing print and electronic materials to communicate information relevant to study activities and results.

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, including costs of a Quality Assurance Manager (see QA/QC policy).

d. Data Accessibility. Specify the costs associated with retaining the data and making it publicly accessible in accordance with HEI’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 four single-spaced pages. The Institute reserves the right not to consider proposals that exceed this limit. Appendices may be provided as supplementary information,
but the 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 and E combined should not exceed 15 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/or what hypothesis is to be tested.

B. Anticipated Results 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 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 (such as cell type, animal strain, or subject population) 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, Form F-11 below).

HEI is committed to research that can lead to a better understanding of the health responses of all members of the general population, particularly the most sensitive. Accordingly, consider the composition of the study population, including gender, racial/ethnic composition, and other aspects that might affect the response, and provide a rationale for the choice of composition.

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 pollutants (and the rationale for their selection), randomization procedures, methods used for any blinding of observations, and the proposed number of observations (including the number of animals or participants and exposure groups), preferably with a power calculation. Describe any new methodology and its advantage over existing methodologies. For in vitro and in vivo exposure studies, methods to generate, monitor, and analyze exposure concentrations and composition should be described in detail. HEI is not enthusiastic about funding studies with older engines and fuels or Standard Reference Materials samples; however, they could serve as positive controls for the proposed experimental treatment.

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

Where appropriate, 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 in HEI Investigator Commitments). However, detailed QA information should not be submitted with the original application but will be requested for successfully funded studies that meet the above criteria.

E. Statistical Design, Analysis Plans, and Access to Data
Provide calculation of statistical power and a justification of the proposed numbers of animals/participants/samples. Include 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 biostatistical reviewer. HEI requires that a statistician is part of the study team, either listed under study personnel or as a consultant. It should be evident that the statistician has reviewed the study
design and data analysis plan. HEI recommends including power calculations where possible. Please note that in addition to reviews by experts in the subject matter, HEI often asks statisticians to review the statistical design of studies.

Investigators should include a plan for data sharing and data accessibility at the end of the study. Please see HEI's Policy on Data Access.

F. Research Translation and Dissemination

The Research Translation and Dissemination Plan describes approaches for providing education and outreach to various sectors, such as community members and policymakers. The plan should outline the team members and other collaborators involved in implementing the plan, and how and to whom results will be communicated, including dissemination beyond academic presentations and publications where possible. The plan should include the insights (e.g., intended and unintended effects) and decision-making applications that the findings can provide as well as the potential limitations, uncertainties, and the factors (e.g., built, natural, socioeconomic, and political) captured or not captured in the research. For applications with community engagement, please cross reference that plan (Form F-7).

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. If a study is recommended for funding, HEI will request a preliminary QA/QC plan to be submitted to HEI on contract initiation. A final approved plan is required within 2 months of the contract start date and before study initiation (i.e., data collection). We recommend that investigators allocate two months at the start of the study period to develop and finalize their Quality Assurance/Quality Control Plan and about three months at the end of the study to write and revise the final report.

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H. Literature Cited

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

COMMUNITY ENGAGEMENT PLAN (FORM F-7 — if applicable)

Proposals where community engagement is indicated must include a two-page Community Engagement Plan for meaningful engagement with community groups as well as other stakeholders that have an interest in the proposed research. Community engagement has many different meanings, can be conducted through a variety of actions to broaden the impact of studies, and benefit the communities involved. Do not exceed two pages.

The plan should provide the following information:

a. **Objectives for engagement.** Discuss how the engagement plan will benefit both the research and members of the community and the anticipated outcomes of implementing the plan.

b. **Anticipated community groups.** Describe the community groups with which applicants plan to collaborate or that the plan will target, as well as the approach that will be used to identify...
interested community members in the study area and other stakeholders to meaningfully advance the impact and relevance of the research.

c. **Approach to engage community groups.** Describe the methods and strategies, as well as the specific roles of participants throughout the study period, to conduct constructive community engagement and foster relationships among collaborators during research. Explain the strategy for lowering barriers to participation for historically marginalized or underrepresented communities. Describe how or if groups will be involved in designing or implementing the 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 occur equitably and through culturally appropriate means.

e. **Research team member expertise.** Describe the team members with the expertise and responsibility to implement the plan, including previous experience with community engagement in environmental health research.

**OTHER SUPPORT (FORM F-8)**

Describe current and pending grants or contracts — whether from public or private sources — from which each of the key investigators included in the proposed project are now drawing or anticipate drawing support, including any in-kind contributions. Identify project by title, agency, or organization supporting such work, and 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-9)**

**A. Facilities**

Describe all the facilities to be used and 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 Project Plan (Form F-6).

**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, on a separate page identify and explain role of any individuals employed by sponsors of HEI (U.S. Environmental Protection Agency, industry, or foundations) who are involved with any aspect of the project. Also, list any resources provided by sponsors (such as facilities or animals).

**BIOGRAPHICAL SKETCHES (FORM F-10)**

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.

**ADDITIONAL SUBMISSIONS (FORM F-11)**

**Human Participants (if applicable)**

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 and additional requirements specified by the EPA. HEI is responsible for ensuring that these guidelines are followed by all Institutions and investigators who receive HEI funds.
HEI

Applicants who request research funds from HEI are asked to indicate on the Title Page (Form F-1, Item 6), whether human subjects or derived materials will be used during their study. If Item 6 of the application has been marked “YES,” applicants should briefly describe the nature of human participation (or use of human data) and indicate whether IRB assurance is already in place or will be requested. Applicants based outside the USA should briefly describe the process for obtaining permission from their Ethics Board or equivalent body that provides such approvals.

Investigators who are selected for funding will need to submit the following to HEI before the study starts: OMB form No. 0990-0263, application to IRB (or equivalent ethics board) and relevant documents, approval from IRB or a statement from the IRB that the study is exempt, and approved informed consent documents, if applicable.

Laboratory Animals (if applicable)
The applicant shall provide with the application written assurance that any use of laboratory animals will comply with the provisions of the Animal Welfare Act (7 U.S.C. S 2131 et. seq.) and the guidelines set forth in the Guide for the Care and Use of Laboratory Animals. These documents are available from the Office for the Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892. When laboratory animals are to be used in the proposed studies, state the species, strains, ages, and numbers of the animals involved and the methods to be used to comply with the above-mentioned guidelines. If approval from the Institutional Animal Care and Use Committee has been obtained, the approval letter should be included with the application. Investigators are also encouraged to read the Animal Research: Reporting of In Vivo Experiments (ARRIVE) Guidelines (see http://www.nc3rs.org.uk/page.asp?id=1357). Although these guidelines pertain to reporting of research, HEI urges investigators to plan animal experiments being cognizant of the ARRIVE recommendations.

Recombinant DNA (if applicable)
Applicants proposing work with recombinant DNA should adhere to the current NIH Guidelines for Research Involving Recombinant DNA Molecules.

Quality Assurance (QA)/Quality Control (QC)
All applicants should provide a high-level summary of the measures in place to ensure the quality of the data collection procedures, data processing procedures and analyses, and data and records management.

Detailed QA/QC information should not be submitted with the original application but will be requested for successfully funded studies. If a study is recommended for funding, HEI will request a preliminary QA/QC plan to be submitted to HEI on contract initiation. A final approved plan is required within 2 months of the contract start date and before study initiation (i.e., data collection). HEI typically contracts an external QA auditor for all studies. See HEI Investigator Commitments and our QA/QC procedures page for more details.

Sponsor Participation
If “YES” has been marked under sponsor participation (i.e., any of the organizations funding HEI) on page F-8 of the application form (Other Support, Form F-8), please explain on a separate sheet the nature of sponsor participation. Identify and explain the role of any individual employed by EPA or industry sponsors of HEI (see www.healtheffects.org/about/sponsors) who is involved with any aspect of the proposed study. Also, list any resources provided by sponsors, including animals, equipment, and facilities. Please note that employees of organizations funding HEI cannot receive funds from HEI for salary or any other costs.

Previous HEI Funding
All principal investigators (and co-PI, if applicable) who previously received HEI funding should include a brief (up to 300 words) summary of previous HEI-funded studies, including key outcomes, successes, and challenges.

Conflict of Interest
In addition to information on sources of Other Support (Form F-8), HEI requires investigators to disclose any personal conflicts of interest. HEI will treat all disclosures as confidential information, which will be used solely in the application review process and not shared outside HEI. 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 and travel costs). 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).

**Letters of Support**

A. **Consultants.** 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.

B. **Statistician.** 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.

C. **Other Letters of Support.** Please provide letters of support where applicable, indicating the type of support the collaborators will provide. Examples include:
   a. Access to facilities
   b. Data sharing
   c. Collaboration with communities or community groups

**Additional Materials (Rosenblith Award only)**

Applications to the Walter A. Rosenblith New Investigator Award should include a cover letter and two letters of reference to be appended to the beginning of the application. Please also include a letter indicating institutional support, a mentoring plan with letters from each mentor, three recent publications, and a list of all publications by the candidate to be included as part of Form F-11. Please refer to the RFA for details.

**PERSONAL DATA (FORM F-12 — OPTIONAL)**

HEI has a continuing commitment to monitoring the operation of its review and award process to detect, and deal appropriately with, real or perceived inequities with respect to age, ethnicity, race, gender, or other personal attributes of the proposed principal investigator. To provide HEI with the information needed to fulfill this commitment, we request that each applicant complete the optional personal data form (Form F-12) and submit it as a separate PDF with the full application. Upon receipt at the HEI office, this form will be separated from the application and used only for internal HEI monitoring procedures. HEI strongly appreciates the completion of this form to support its efforts to track the diversity of applications and funded investigators and to expand investment into diversity, equity, and inclusion as part of its **2020 action plan.** 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.