

## CEEH Pilot Project Funding

### Call for Pre-Applications for the Center for Ecogenetics and Environmental Health (CEEH)

**Pre-Applications Due Date: 12/01/14**

**Notification of Invitation to Submit a Full Application: 12/08/14**

**Invited Full Applications Due Date: 1/30/15**

These pilot project grants are designed to assist investigators in obtaining preliminary data that will be useful for competitive, full-scale grant applications in the area of gene-environment interaction (GxE). The CEEH especially encourages applications that focus on the role of human genetic and epigenetic variation as modifiers of environmentally induced diseases. These grants may also focus on research-based GxE outreach activities, or the ethical, legal and social issues surrounding GxE research. An official budget ceiling has been established at \$35,000 for Direct Costs. Applications with budgets in excess of \$35,000 will not be considered. Indirect costs should not be included in the proposed budget. More information about the CEEH mission and goals can be found on the CEEH web site at <http://depts.washington.edu/ceeh/>.

## PURPOSE

**BACKGROUND:** The UW Center for Ecogenetics and Environmental Health (CEEH) is an Environmental Health Sciences (EHS) Core Center of the National Institute of Environmental Health Sciences (NIEHS). The theme of the CEEH is "Mechanisms Underlying Human Variability in Response to Environmental Exposures". The interactions between genetics and environment are complex, and defy explanation through traditional disciplinary pathways of investigation. Recent developments in molecular biology provide exciting new tools that can be used directly in human populations to unravel the molecular basis for genetic differences in susceptibility to environmental hazards (ecogenetics). The purpose of the CEEH is to provide an administrative infrastructure and technical support to foster the multidisciplinary collaborations necessary to extend basic studies on environmental health problems to direct application in human populations. The purpose of the Pilot Projects program in the CEEH is to provide funding for pilot data necessary to successfully apply for NIH funding relevant to the mission of the CEEH and the NIEHS. Pilot projects applications should directly address scientific questions of interest to both the CEEH and the NIEHS (for information about areas of research interest for the NIEHS go to: <http://www.niehs.nih.gov/about/od/strategicplan/strategicplan2006/index.cfm>.)

Questions concerning the relevance of a proposed research topic should be directed to Dr. Terry Kavanagh, CEEH Director (email: [tjkav@uw.edu](mailto:tjkav@uw.edu); phone: 685-8479).

The CEEH consists of 6 Areas of Research Emphasis (ARE):

1. Genomics of Xenobiotic Disposition
2. Environmental Mutagenesis and Carcinogenesis
3. Susceptible Populations
4. Neurotoxicology and Neurodegenerative Disease
5. Cardiovascular Toxicology
6. Exposure Sciences

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Each of these Areas of Research Emphasis includes 5-9 affiliated Environmental Health Sciences (EHS) Core Investigators and 2-9 affiliated Clinical and Translational Sciences (CTS) investigators representing several different schools, departments, and programs throughout the UW and FHCRC.

The CEEH provides its investigators and pilot project awardees with access to three Facility Cores:

1. The **Functional Genomics and Proteomics Facility Core**: State-of-the-art molecular biology tools and resources to assist in the conduction of large-scale molecular biomarker work involving human populations, animal disease models, and various tissues (targeted DNA NextGen sequencing, exome sequencing, targeted NextGen RNA sequencing, RNA-Seq, ChIP-Seq, BS-Seq, qRT-PCR, targeted methylation analysis, genotyping, oligonucleotide microarray processing for mRNA and microRNA profiling, targeted protein detection, phosphoprotein analysis, and ProtoArray® Human Protein Microarray analysis.
2. The **Integrative Environmental Health Sciences Facility Core (IEHSFC)**: Population-based translational health sciences including clinical assessments, sample storage, technical assistance and access to many facility core laboratories throughout the UW and FHCRC. The Bioinformatics & Biostatistics Unit (BBU) of the IEHSFC provides comprehensive statistical and bioinformatics analysis of OMICs data (e.g. microarray, RNA-Seq, ChIP-Seq, metabolomics and proteomics data, etc.), including pathway analysis.
3. The **Exposure Assessment, Biomarkers and Metabolomics Facility Core**: Development and application of exposure assessment tools and biomarkers; application of metabolomics technologies to gene-environment (GxE) interaction studies.

Pilot project applications that propose to utilize one or more of the Facility Cores of the CEEH receive favorable consideration. A list of Facility Core Directors is included at the end of these guidelines and more information about the Cores is available on the CEEH Website at:

<http://depts.washington.edu/ceeh/members/core-services.html>

A well-established **Community Outreach and Ethics Core (COEC)** also provides CEEH Investigators with assistance in public engagement and research translation activities. This can include helping investigators identify and connect with stakeholders relevant to their research projects, helping investigators build relationships with specific communities, or helping investigators develop materials or host events to share important research findings with community groups, public health professionals, policy-makers or K-12 teachers and students. The COEC also places particular emphasis on identifying and addressing the ethical, legal and social issues (ELSI) related to EHS and ecogenetics research.

**PROJECTS OF INTEREST:** The following examples suggest the breadth of research questions potentially of interest to the CEEH and the NIEHS. This list is only a sample, and is not inclusive of all the projects that may be considered favorably.

Emerging EHS research areas such as:

- Epigenetics and epigenomics
- Nutrition & diabetes as modifiers of toxicant response
- Microphysiological systems/3D organotypic models for assessing toxicity *in vitro*
- Systems toxicology
- Computational toxicology
- The role of the microbiome as a modifier of toxicant response

Molecular epidemiology studies evaluating the role of a particular gene or a gene combination, which may interact with a component of the environment to cause human disease, including but not limited to:

- Biotransformation enzyme polymorphisms

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- Oncogenes
- Tumor suppressor genes
- Receptor variants
- Genes involved in cell signaling in response to environmental stimuli
- Development and/or application of molecular biomarkers of exposure or effects from environmental factors

Applications of biomarkers to individuals at high risk for developing a chronic disease from an environmental exposure to pollutants, including but not limited to:

- Epigenetic markers indicative of chromatin remodeling
- Enzyme activities or low molecular weight metabolites in peripheral blood
- Circulating exosome-based biomarkers
- Markers of DNA damage
- Urinary components indicative of biological effects, and others

Studies of individuals and families at increased risk for a chronic disease, or development of appropriate animal models to evaluate the interaction of genes and environment (occupation, diet, smoking, pollutants, etc.) in the development of a disease, such as, but not limited to:

- Various cancers
- Chronic neurological disease, such as Alzheimer's and Parkinson's diseases
- Respiratory diseases such as asthma, chronic obstructive pulmonary disease
- Diabetes
- Liver diseases
- Cardiovascular diseases
- Kidney diseases
- Disorders of the reproductive system

Projects promoting meaningful public engagement in EHS and gene-environment interactions research, such as, but not limited to:

- Developing partnerships with affected communities that might lead to Community Based Participatory Research projects
- Development of research translation and dissemination print and/or electronic materials for non-scientific audiences or publications
- Planning and convening workshops, public forums, or community events on topics relevant to the theme and mission of the CEEH

Projects exploring the ethical, legal, and social issues (ELSI) related to EHS and ecogenetics research, such as, but not limited to:

- Insurance restrictions based on genetic susceptibility to environmental factors
- Reliability of genetic testing / policy and regulations
- Workplace discrimination based on genetic testing for occupational susceptibility
- Human subjects issues relating to genetic testing and return of research results

## **APPLICATION PROCESS DETAILS**

**Pre-Applications:** Eligible Investigators (see below for a definition of an Eligible Investigator) are requested to submit by **December 1, 2014** a three-page Pre-Application Form (available on the CEEH Website at <http://depts.washington.edu/ceeh/about/pilot-projects.html>) containing a brief description of

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the project, its relevance to the mission of the CEEH and NIEHS, and the proposed Specific Aims, to Ms. Elizabeth Guzy ([eguzy@uw.edu](mailto:eguzy@uw.edu)). The CEEH Pilot Projects Review Committee will evaluate these Pre-Applications for relevance to the mission of the CEEH and the NIEHS. Investigators submitting Pre-Applications that are deemed to be responsive to this announcement will be so notified on December 8<sup>th</sup>, 2014 and they will be requested at that time to submit a full proposal application. **The deadline for receipt of full proposal applications is January 30, 2015 at 5:00 PM PST.** Full proposal applications must be routed through the Investigator's Department Chair (and College Dean if DOM/SOM) for signatures of endorsement. **Full proposal applications are not submitted through the Office of Sponsored Programs; therefore an e-GC-1 form is NOT required.** In preparing your full proposal, please keep in mind that it will be read by a committee of faculty and outside experts selected from the general area in which the proposal is made, but not all reviewers are necessarily specialists in the particular field of research being proposed. As part of the application form, you will be asked to suggest appropriate reviewers for your proposal.

**Your complete application should include the following five components:**

1. A completed "CEEH Pilot Project Grant Application" form (will be emailed to you upon invitation)
2. A proposed budget (on PHS398 Budget Form) and a budget justification (on PHS398 Budget Justification Form). Use budget categories to define types of expenditures. Where normal increases in salaries are anticipated, the required amounts must be included in estimates. Include applicable fringe benefits. The budget should show all persons, paid or unpaid, who will carry out the research. The function of these persons should be explained in the justification. Also itemize and/or justify major cost items. Administrative salaries cannot be covered. Equipment will be supported only if tied directly to the research project and equipment costs may not exceed \$5,000 except in exceptional circumstances. **Subcontracts are not allowable. No indirect costs (F&A) will be provided (i.e. the budget should be calculated on the basis of direct costs only).**
3. A current NIH Biosketch for the Principal Investigator and any co-PIs (not to exceed three pages each) and a list of any additional key personnel
4. A complete list of current and pending funding, including project title, source, amount and period of funding. If the proposed project is being partially supported by other sources, please specify source and amount of support.
5. A written proposal describing your project which includes the elements described below

Combine these five documents in the order listed above into a single PDF and submit via email to [eguzy@uw.edu](mailto:eguzy@uw.edu) by **Friday, January 30, 2015 at 5:00 pm PST**. General questions about this RFA should be directed to Elizabeth Guzy (206-685-5333, [eguzy@uw.edu](mailto:eguzy@uw.edu)).

**Your written proposal (#5 above) must include:**

**An abstract** (not to exceed 300 words) describing the proposed research project and how it relates to the goals of the CEEH; include a statement about the clinical importance of the work, if appropriate. (The abstract should be on a separate page and does not count towards the page limit described below.)

**An outline of your concise research plan** that is no longer than four single-spaced or ten double-spaced pages (11 point Arial font). **PROPOSALS EXCEEDING THIS LIMIT WILL NOT BE ACCEPTED.** This page limit count does not include bibliography or reprints. This outline should include the following sections:

- I. Introduction:

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- a. Objective: State the overall objective or long-term goal of the proposed research as it relates to one or more of the 6 Areas of Research Emphasis of the CEEH or the Community Outreach and Ethics Core.
  - b. Background: Review the most significant previous work in this area and describe the current status of research, including your own, in this field.
  - c. Rationale: Present concisely the justification for your approach to the problem if it is not obvious from the preceding material.
- II. Specific Aims: List your objectives for the period of requested support.
  - III. Method of Procedure: Give details of your research plan, including a description of the experiments or other work you propose to do; the methods, species of animals (where appropriate), and techniques you plan to use; the data you expect to obtain; and the means by which you plan to analyze or interpret the data to attain your objectives. Include, if appropriate, a discussion of any pitfalls you might encounter, and the limitations of the procedures you propose to use.
  - IV. Significance: Discuss the potential importance of the proposed work and any novel ideas or contributions in terms of ecogenetics and environmental health. Discuss consistency of the proposal with the mission and objectives of the CEEH research AREs or COEC.
  - V. Facility Core/Technology Access Usage: Briefly list facilities and major items of equipment available for this work, either through CEEH core services or through subsidized access to other UW Cost Centers. If you are proposing to use CEEH Core services, discuss the nature and extent of such use. It is recommended that you discuss your project in advance with the Facility Core director(s) to ensure that the Core will be able to provide the necessary service.
  - VI. Collaborative arrangements: If the proposed project requires collaboration with other institutions, community organizations, or any group whose cooperation is essential, describe this collaboration and provide evidence to assure the reviewers that those involved support the proposed project. Please note that sub-contracts are not allowed and all awarded funds must be spent through UW or FHCRC mechanisms. International projects are not allowable.

**SPECIFIC PROVISIONS:**

1. An official budget ceiling has been established at \$35,000 for Direct Costs. **Applications with budgets in excess of \$35,000 will not be considered. Indirect costs should not be included in the proposed budget.**
2. While the CEEH will review more than one proposal by a given Principal Investigator or Co-Principal Investigator during a single review period, the decision to fund more than one proposal will reside with the Final Review Committee (which consists of the CEEH Internal Advisory Committee). This decision will be based in part on the amount of overlap in the proposals, the need to provide a fair distribution of funds to all investigators, and the level of funding already available to the applicant(s). In general, multiple submissions by a single or group of investigators during any single review period is discouraged.
3. Where possible, the personnel for research should be drawn from the ranks of students working on advanced degrees. These students may be hired at 50% FTE (the regular status of a Graduate Research Assistant). Hourly help support is also acceptable. Please note that substantial savings may be realized by the use of Work Study students.
4. **Notification of award will be sent by e-mail March 23, 2015.** The budget year will be April 1, 2015 through March 30, 2016.

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5. **Projects may be funded for a maximum of twelve months.** The Principal Investigator is responsible for the proper administration of funds. Each award will be assigned a dedicated budget number (a sub-budget to the CEEH Parent budget). Funds may not be transferred between projects. The CEEH will monitor expenses on the project and provide budget projections and other support as requested, but will not assume fiscal responsibility for over expended budgets.

## **REVIEW CRITERIA AND COMMITTEE DETAILS**

The CEEH is committed to providing career development and mentoring for young investigators. Priority will be given to junior faculty (Assistant Professor) applicants IF there are adequate numbers of junior faculty proposals that meet relevancy requirements and are of adequate scientific quality.

Primary reviewers will be one expert from UW and one from outside the institution. Review procedures are similar to those used by NIH grant review committees. **Investigators will be notified of Review Committee results by e-mail by March 23, 2015. Please do not call the CEEH before this time.**

Funded projects involving either human subjects or vertebrate animals must obtain approval from the appropriate University committee before a budget can be established. Approval is not required until a project has been funded. For information on vertebrate animal use in research, please visit the UW Office of Animal Welfare web site at: <http://depts.washington.edu/oawhome/>

For information on human subjects, please visit the UW Human Subjects Division website at: <http://www.washington.edu/research/hsd/>

**EVALUATION CRITERIA:** (Percentage figures refer to the relative weight each criterion will be given when making funding decisions.):

1. **The relevance of the proposed research to the theme, mission, and goals of the CEEH and NIEHS** must be clearly described. The intent of the CEEH is to provide initial funding of new projects that could lead to an NIH R21/R01 application that would logically be assigned to the NIEHS. It is expected that applicants will eventually seek outside grant support for continuation of their research programs. (30%)
2. **The scientific merit of the proposed research and its feasibility** are critical factors that will be used in evaluating an application. Projects that may result in a scientific publication after project completion will be considered for funding, as well as more preliminary work likely to lead to successful procurement of a full study grant from an outside source in the future. (30%)
3. The CEEH is committed to providing career development and mentoring for young investigators. Proposals that support these investigators' research will be accorded special consideration. (20%)
4. The CEEH provides access to three facility cores: *Functional Genomics and Proteomics, Integrative Environmental Health Sciences, and Exposure Assessment, Biomarkers and Metabolomics*. **Use of these Facility Cores, as well as efforts to learn the various techniques they employ, is encouraged.** Pilot Project applicants are encouraged to discuss their projects with Facility Core Directors prior to submission, if substantial use of a Core is proposed. A list of Facility Core Directors is included at the end of these guidelines. (20%)

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5. (For COEC and ELSI Related Applications Only – this criterion will replace #4 for evaluation purposes) Projects that can demonstrate **active collaboration with COEC staff, creative and innovative use of COEC resources, and meaningful involvement of CEEH investigators** will be given priority. (20%)

## **ELIGIBILITY**

Only faculty members from the **University of Washington** or **Fred Hutchinson Cancer Research Center** holding one of the following ranks are eligible to serve as Principal Investigator on a Pilot Project proposal:

- Assistant Professor
- Associate Professor
- Professor
- Research Assistant Professor
- Research Associate Professor
- Research Professor

Individuals holding a UW Affiliate Faculty appointment are not eligible. UW or FHCRC faculty members who hold one of the above titles, but who are not currently members of the CEEH, must collaborate with an EHS Core Investigator already affiliated with the CEEH who agrees to serve as a sponsor of the proposal. A list of current CEEH ARE Directors is included at the end of these guidelines and a complete list of CEEH membership is online at:

[http://depts.washington.edu/ceeh/research\\_members.html](http://depts.washington.edu/ceeh/research_members.html)

## **REPORTING REQUIREMENTS**

It is expected that an oral or poster presentation of progress on funded Pilot Projects will be made at the Annual CEEH Meeting (date and location for 2015 to be determined). A Written progress report is required at the end of the project period so the results can be included in the CEEH Annual Progress Report for that year. The Pilot Projects awarded for this round will be required to submit a final report by May 1, 2016. **If publication(s) result, directly or indirectly, from award allocations, they must carry an acknowledgement of the source of such support from the UW NIEHS sponsored Center for Ecogenetics and Environmental Health, Grant #: NIH/NIEHS P30ES007033. Please help us continue to support your research by citing our grant number in all publications we support.** Please send a reprint of the publication and/or the URL to Elizabeth Guzy ([eguzy@uw.edu](mailto:eguzy@uw.edu)) or c/o the Center for Ecogenetics and Environmental Health, UW Box 354695.

## CONTACT INFORMATION

General questions about this RFA should be directed to Elizabeth Guzy (206-685-5333; [eguzy@uw.edu](mailto:eguzy@uw.edu)).

### ARE Directors

#### Genomics of Xenobiotic Disposition

Evan Gallagher, [evang3@uw.edu](mailto:evang3@uw.edu), 206-616-4739

#### Environmental Mutagenesis and Carcinogenesis

Chris Kemp, [cjkemp@uw.edu](mailto:cjkemp@uw.edu), 206-667-4252

#### Susceptible Populations

Elaine Faustman, [faustman@uw.edu](mailto:faustman@uw.edu), 206-685-2269

#### Neurotoxicology and Neurodegenerative Disease

Lucio Costa, [lgcosta@uw.edu](mailto:lgcosta@uw.edu), 206-543-2831

#### Cardiovascular Toxicology

Mike Rosenfeld, [ssmjm@uw.edu](mailto:ssmjm@uw.edu), 206-543-1738

#### Exposure Sciences

Mike Yost, [airion@uw.edu](mailto:airion@uw.edu), 206-685-7243

### Facility Core Directors and Contacts

#### Integrative Environmental Health Sciences Facility Core (IEHSFC)

Director, Joel Kaufman, [joelk@uw.edu](mailto:joelk@uw.edu), 206-616-3501

Clinical & Translational Services Unit (CTSU) Director, Catherine Karr, [ckarr@uw.edu](mailto:ckarr@uw.edu), 206-616-4355

CTSU Manager, Karen Jansen, [kjansen@uw.edu](mailto:kjansen@uw.edu), 206-616-6525

Bioinformatics & Biostatistics Unit (BBU) Director, Katie Kerr, [katiek@uw.edu](mailto:katiek@uw.edu), 206-543-2507

BBU Manager, Theo Bammler [tbammler@uw.edu](mailto:tbammler@uw.edu), 206-616-7378

#### Functional Genomics and Proteomics Facility Core (FGPFC)

Director of Proteomics, Jing Zhang, [zhangj@uw.edu](mailto:zhangj@uw.edu), 206-897-5452

Co-Director of Genomics, John Stamatoyannopoulos, [jstam@uw.edu](mailto:jstam@uw.edu), 206-685-2672

FGPFC Manager, Theo Bammler, [tbammler@uw.edu](mailto:tbammler@uw.edu), 206-616-7378

#### Exposure Assessment, Biomarkers, and Metabolomics Facility Core (EABMFC)

Director of Biomarkers, Chris Simpson, [simpson1@uw.edu](mailto:simpson1@uw.edu), 206-543-3222

Co-Director of Metabolomics, Yvonne Lin, [yvonlin@uw.edu](mailto:yvonlin@uw.edu), 206-685-8718

Co-Director of Exposure Assessment, Rich Fenske, [rfenske@uw.edu](mailto:rfenske@uw.edu), 206-543-0916

EABMFC Manager, Theo Bammler, [tbammler@uw.edu](mailto:tbammler@uw.edu), 206-616-7378

#### Community Outreach and Ethics Core (COEC)

Director, Kelly Edwards, [edwards@uw.edu](mailto:edwards@uw.edu), 206-221-6622

COEC Manager, Marilyn Hair, [marhair@uw.edu](mailto:marhair@uw.edu), 206-685-8244