

ANNOUNCEMENT

Environmental Health Research Pilot Project Grants

Grants up to \$50,000 available

The Southern California Environmental Health Sciences Center (SCEHSC, scehsc.usc.edu) is pleased to announce the 2020 Pilot Projects Program, supporting **one-year research projects** that aim to promote the understanding of environmental exposures and human disease. The goal of the program is to provide investigators with an opportunity to collect preliminary data and/or validate the utility of specific methods or techniques to establish the feasibility of larger-scale research projects and ultimately seek external (especially NIEHS) funding.

The SCEHSC is seeking investigator-initiated applications from all environmental health research areas. Topics of special interest include:

New Approaches for Exposure Assessment	Environmental Contributions to Obesity and Metabolic Dysfunction
New Approaches for Environmental Disaster Response Research	Application of Omics Technologies to Environmental Health Research
Climate Change, Adaptation, and Environmental Health	Complex Mixtures in Environmental Health
Environment, Neurodevelopment, and Neurological Diseases	Human Microbiome and the Environment
Novel Approaches in Environmental Disparities Assessment	

➔ **Individuals with a faculty appointment** in any department or school/division at USC, CHLA, UCLA or Caltech are eligible to apply.

LETTER OF INTENT & SPECIFIC AIMS

Prospective applicants will submit a one-page Letter of Intent (LOI) along with one page of final Specific Aims (SA). The LOI will include the project title, a brief summary of project objectives, and identification of the key participating investigators. **All proposed projects should have a clear and identifiable environmental health emphasis.** Please e-mail Letters of Intent and Specific Aims to Vivian Lee, viv.lee@usc.edu, by the LOI deadline.

FULL PROPOSAL

Successful LOI applicants will be invited to submit a full proposal for up to \$50,000 of funding. Instructions for full proposal submission can be found below and on the SCEHSC Pilots webpage (scehsc.usc.edu/2020-pilots). Please email full applications as one PDF file to Vivian Lee, viv.lee@usc.edu, by the full proposal deadline.

SOUTHERN CALIFORNIA ENVIRONMENTAL HEALTH SCIENCES CENTER

• Keck School of Medicine of USC • 2001 N Soto Street, MC 9237, Los Angeles, CA 90089 • TEL (323) 442-1096 FAX (323) 442-3272 •

Deadlines and Notification Schedule

Request for Applications	LOI & SA Deadline	LOI Notification	Full Proposal	Award Notification	Award Start Date
July 29, 2019	August 26, 2019 at 5:00 PM	September 3, 2019	September 17, 2019 at 5:00 PM	December 2019	April 1, 2020

FULL APPLICATION INSTRUCTIONS:

Invited Full Applications should include the following, in this order:

1. **Cover Sheet** – including the full title of the project; name, contact information, institution, and department of the Principal Investigator; and the name, institution, and department of any co-investigators or faculty sponsors
2. **Project Abstract (300 words or less)** – a brief summary of the project
3. **Specific Aims (1 page)** – concise goals of the proposed research and a summary of expected outcomes, including specific objectives
4. **Research Strategy (6 pages MAXIMUM, not including references)**
 - i. **Significance** – describe the importance of the problem or critical barrier that the project addresses, and explain how the project will improve scientific knowledge, technical capability, or clinical practice if the proposed aims are achieved
 - ii. **Innovation** – describe how the proposed research seeks to shift research practice paradigms and how any methodologies or theoretical concepts that are being developed or used in the project may have an advantage over existing practices
 - iii. **Approach** – describe the overall strategy, methodology, and analyses to be used to accomplish specific aims, including how data will be collected. Discuss potential problems, alternative strategies, and benchmarks of success.
5. **Grant Potential (1 page)** – clear description of how a successful pilot project and/or expansion of the project will lead to an R01 (or equivalent) submission
6. **Project Timeline (1 page)** – a proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the 12-month period of performance
7. **Budget** – an NIH-style budget table of personnel, equipment, supplies, travel, and other estimated costs to perform the proposed project. [Applicants may budget up to \$50,000 for direct costs. Indirect (F&A) costs should be listed separately from direct costs.]
8. **Budget Justification** – a detailed explanation and justification of the funding request
Non-allowable expenses:
 - i. Salaries for Associate and Full Professors
 - ii. Tuition for graduate students

9. **NIH-Format Biosketches** – for the PI and Co-Investigators (5 page limit per investigator)

10. **Required if human subjects research (see appendix)** –

- a. NIH-Format Protection of Human Subjects section
- b. NIH-Format Planned Inclusion Enrollment Report
- c. Human Subjects training documentation for the PI and Co-Investigators (CITI Human Subjects Training)
- d. If clinical trial, a data safety monitoring plan is also required

11. **Facility Core Usage and Correspondence** – The Southern California Environmental Health Sciences Center (SCEHSC) offers technical support to Center investigators and Pilot Project awardees. A wide range of capabilities, including biostatistical support, analytical sample preparation/processing, and biological sample measurements are available. For more information on the Center’s Facility Cores, please read the core descriptions on our website, scehsc.usc.edu. Early discussion with Core Directors is strongly encouraged. SCEHSC Facility Core Directors should be contacted to provide an electronic letter of support as part of the full project application submission. **If facility cores are NOT proposed to support Pilot Project performance, written justification must be provided in the project application.**

Core Directors may be contacted as follows:

- A. Integrative Health Sciences Facility Core (Director: Carrie Breton, ScD, breton@usc.edu)
- B. Biostatistics Facility Core (Director: Jim Gauderman, PhD, jimg@usc.edu)
- C. Spatial and Exposure Analytics Core (Director: Ed Avol, MS, avol@usc.edu)

REPORTING REQUIREMENT:

The anticipated period of funded project performance will be April 1, 2020 through March 31, 2021. **IRB/IACUC approval letters must be received by January 15th to avoid any delays in funding.** Funded projects will be expected to submit initial IRB applications immediately following the notice of award. All funded projects, along with IRB approval, must be reviewed and approved by NIEHS prior to the funding start date.

Please note that pilot projects involving work outside of the U.S. are subject to NIEHS and State Department approval. This includes any proposed use of samples previously collected outside of the U.S. Pilot project grantees should plan accordingly, as applications for foreign clearance may take several weeks to process.

In addition, all pilot project grantees are required to submit an **Annual Progress Report each fall**. The progress report will contain updates on the project, publications directly related to findings from the project, and grants directly associated with project results. Grantees may be asked to **present a poster or short oral presentation** on pilot progress at a monthly Center executive committee meeting or symposia dedicated to pilot project grantees.

All publications resulting from pilot funding must include the following acknowledgement:

“This work was supported by the Southern California Environmental Health Sciences Center, grant # P30ES007048.”

APPLICATION REVIEW CRITERIA:

Applications will be reviewed by a multidisciplinary panel of scientists. Awardees will be selected following the review, and **funding will begin April 1, 2020**. Notification of award will be in December 2019.

The major review criteria are:

1. Relevance to environmental health and potential to identify solutions to environmental health problems
2. Scientific quality
3. Stimulation of interdisciplinary activity
4. Likelihood that the project will lead to R01 or other external funding
5. Novelty of ideas

For questions or more information, contact:

Vivian Lee (323) 442-1096 / viv.lee@usc.edu

or

Lisa Wolff (323) 442-2750 / lisa.wolff@usc.edu

APPENDIX

Instructions for Human Subjects Research Additional Requirements

1. NIH-Format Protection of Human Subjects section

For non-exempt studies: The NIH-Format “Protection of Human Subjects” section is required.

In summary, the “Protection of Human Subjects” section should include the following. **For complete instructions, see Section 3.1 of the [NIH Application Guide](#).**

1. Risks to Human Subjects
 - a. Human subjects involvement and characteristics; vulnerable populations
 - b. Sources of materials – what, how, access to identifiers
 - c. Potential Risks – physical, psychological, social, etc.
2. Adequacy of Protection Against Risks
 - a. The consent process
 - b. Procedures to minimize risks
 - c. Additional protections for vulnerable subjects
3. Potential Benefits of Proposed Research to Research Participants and Others
 - a. May not be direct benefit to subjects
 - b. Discuss risks in relation to anticipated benefits
 - c. Should not include monetary compensation
4. Importance of the Knowledge to be Gained
 - a. Discuss knowledge in relation to risks

For exempt studies: The full NIH-format “Protection of Human Subjects” section is NOT required. Instead, please provide the following:

1. Description of study
2. What human data/ samples will be used
3. Where these data/ samples will be obtained from

2. NIH-Format Planned Inclusion Enrollment Report

NIH-format Planned Inclusion Enrollment Reports are required for all **non-exempt** human subjects studies. NIH instructions can be found [here](#) and a fillable PDF form can be downloaded [here](#).

3. Human Subjects Training Documentation

CITI Human Subjects Training Certificates are required for the PI and all Co-Investigators for any human subjects study (exempt and non-exempt).

4. NIH-Format Data Safety Monitoring Plan (required ONLY if pilot is a clinical trial)

If the pilot is a clinical trial, the NIH-Format “Data and Safety Monitoring Plan” is required. **For complete instructions, see Section 3.3 of the [NIH Application Guide](#).**

In summary, the “Data and Safety Monitoring Plan” should include the following:

1. Overall framework for data and safety monitoring commensurate with risk
2. Responsible party for monitoring
3. Procedures for reporting Adverse Events/Unanticipated Problems
4. Trial monitoring by individual(s) or group:
 - a. Data and Safety Monitoring Board (DSMB) required for multi-site trials with greater than minimal risk, and generally, for all Phase III trials