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 2019 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:

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<th>New Approaches for Exposure Assessment</th>
<th>Environmental Contributions to Obesity and Metabolic Dysfunction</th>
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<td>New Approaches for Environmental Disaster Response Research</td>
<td>Application of Metabolomics to Environmental Health Research</td>
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<td>Climate Change, Adaptation, and Environmental Health</td>
<td>Complex Mixtures in Environmental Health</td>
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<td>Environment, Neurodevelopment, and Neurological Diseases</td>
<td>Human Microbiome and the Environment</td>
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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 Remy Landon, rlandon@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 website (scehsc.usc.edu) under the Pilot Projects tab. Please email full applications as one PDF file to Remy Landon, rlandon@usc.edu, by the deadline.

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<th>Deadlines and Notification Schedule</th>
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<td>Request for Applications</td>
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Supported by the National Institute of Environmental Health Sciences (NIEHS) Grant # 5 P30 ES007048-23
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 Corps, 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, 2019 through March 31, 2020. **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.

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, 2019.** Notification of award will be in December 2018.

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:**

Remy Landon (323) 442-0492 / rlandon@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