



ENVIRONMENTAL HEALTH PILOT PROJECTS PROGRAM

Grants up to \$50,000

The **Southern California Environmental Health Sciences Center (SCEHSC)** and **USC Center for Translational Research on Environmental Health (USC R-TEN)** is pleased to announce the **2022 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. *Special consideration will be given to early-stage investigators.*

The SCEHSC is seeking investigator-initiated applications from all environmental health research areas.

Special topics of interest:

Cancer and Environment
Environment and Metabolic Diseases including Human and Experimental Approaches (Additional Funds Available*)
<i>Climate Change, Adaptation and Environmental Health</i> (The SCEHSC intends to fund at least one pilot project in this research area.)

Additional Areas of Center Interest:

New Approaches for Exposure Assessment	Complex Mixtures in Environmental Health
New Approaches for Environmental Disaster Response Research	Environmental Contributions to Obesity and Metabolic Dysfunction
Environment, Neurodevelopment, and Neurological Diseases	Application of Omics' Technologies to Environmental Health Research
Novel Approaches in Environmental Disparities Assessment	Community-Based Participatory Research

Eligibility

Individuals with a full-time faculty appointment in any school at the USC are eligible to apply. Applicants are encouraged to pursue multidisciplinary collaborations, including with investigators at other institutions affiliated with the Center (UC Irvine, UCLA, UC Riverside, UCSD, Caltech, CSUN, Kaiser Permanente Southern California, and CHLA).

Additional Funds

Postdoctoral researchers at USC with a full-time faculty sponsor may submit proposals for up to \$10,000 in direct costs, subject to the same application requirements and deadlines.

*Proposals which incorporate **translational research on environment and metabolic diseases including human and experimental approaches** may submit proposals up to \$90,000 in direct costs.

Key Program Dates

Request for Applications	Aug. 10, 2021
Letter of Intent & Specific Aims Deadline	Sept. 8, 2021
Invitation to Submit Application	Sept. 13, 2021
Full Application Deadline	Oct. 11, 2021
Notification of Award	Jan. 2022
Anticipated Award Start Date	Feb. 1, 2022

For questions for more information, please contact
Sarah Rock (srock@usc.edu)

Full proposal guidelines available at:
<https://scehsc.usc.edu/2022-pilots/>

Non-Binding Letter of Intent & Specific Aims

Prospective applicants must submit a non-binding, one-page Letter of Intent along with one page of final Specific Aims. The letter should include the project title, a brief summary of project objectives, 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 as one PDF file to Sarah Rock, srock@usc.edu, by the deadline, **September 8, 2021** at 5pm Pacific Time.

Successful Letter of Intent applicants will be invited to submit a full proposal for up to \$50,000 (\$10,000 for postdoctoral applicants). For proposals involving translational research including both human and experimental approaches, up to \$90,000 is available- see below. Instructions for full proposal submission can be found below and [on the SCEHSC website](#). Please email full applications as one PDF file to Sarah Rock, srock@usc.edu, by the application deadline, **October 11, 2021** at 5pm Pacific Time.

Translational Component

For proposals which incorporate a translational research design including both human and experimental models (in vitro/in vivo experimental), additional funds (up to \$90,000 total) will be available.

Please contact Dr. Leda Chatzi, chatzi@usc.edu, for questions regarding proposals of translational design.

Eligibility

Individuals with a full-time faculty appointment in any department or school at the University of Southern California (USC) are eligible to apply.

Postdoctoral researchers from USC are also eligible and may request up to \$10,000 in direct costs. Postdoctoral applicants are required to have a full-time USC faculty member as a faculty sponsor as part of their application.

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 (PI); 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 or less)** – 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 or less)** – A proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the 13-month period of performance.
7. **Budget** – A budget table of personnel, equipment, supplies, travel, and other estimated costs to perform the proposed project. Additional direct costs to the award resulting from indirect (F&A) costs associated with any subcontract to other universities must be included within the \$50,000 (or \$90,00 for proposals involving translational research including human and experimental approaches). Postdoctoral applicants may budget up to \$10,000 for 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. Salaries for investigators and staff at institutions outside of USC
 - iii. Tuition for graduate students
9. **NIH-Format Biosketches** – For the PI, co-investigators and faculty sponsors (5-page limit per investigator).
 10. **Facility Core Usage and Correspondence** – The SCEHSC provides technical support to our 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](#). 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:

- Integrative Health Sciences Facility Core (Director: Carrie Breton, PhD, breton@usc.edu)
- Biostatistics Facility Core (Director: Jim Gauderman, PhD, jimg@usc.edu)
- Exposure Factors Facility Core (Director: Ed Avol, MS, avol@usc.edu)

11. Required if human subjects research (see Appendix I) –

- i. NIH-Format Protection of Human Subjects section
- ii. NIH-Format Planned Inclusion Enrollment Report
- iii. Human Subjects training documentation for the PI, co-investigators and faculty sponsors (CITI Human Subjects Training)
- iv. If clinical trial, a data safety monitoring plan is also required

12. Required if proposal includes foreign component (see Appendix II for description of foreign component):

- a. Brief description of research activities at foreign site(s):
- b. Complete institution address
- c. Email, and phone numbers of contact PI at foreign site(s):
- d. Amount of funds going to each foreign site:
- e. Are human or animal subjects involved at the foreign site(s)?

- f. Institutional Federal Wide Assurance Number, IRB, or IEC approval for work performed at foreign site(s):
- g. Will the collaboration with investigators at the foreign site(s) result in co-authorship?

Reporting Requirements

The anticipated period of funded project performance will be February 1, 2022 through February 28, 2023. IRB/IACUC approval letters must be received as soon as possible to avoid any delays in funding. Funded projects will be expected to submit initial IRB applications immediately following the notice of award. Funded projects which include a foreign component will be required to undergo review by NIEHS (see Appendix II for description of foreign component and additional application requirements).

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 an SCEHSC workshop 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, NIEHS grant #P30ES007048."

Application Review Criteria

Applications will be reviewed by a multidisciplinary panel of scientists. Awardees will be selected following the review, and **funding is anticipated to begin February 1, 2022**. Notification of award will be in January, 2022.

The major review criteria are:

1. Relevance and potential to identify solutions to environmental health problems;
2. Scientific quality, approach and significance;
3. Stimulation of interdisciplinary activity, particularly with other centers, initiatives, or programs;
4. Likelihood of leading to R01 or other external funding;
5. Novelty and innovation of ideas.

For questions or more information, please contact:

Sarah Rock, srock@usc.edu

APPENDIX

I. Instructions for Human Subjects Research Additional Requirements

A. 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

B. 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](#).

C. Human Subjects Training Documentation

CITI Human Subjects Training Certificates are required for the PI and all co-investigators and faculty sponsors for any human subjects study (exempt and non-exempt). **CITI training must be up-to-date at time of application submission and must be active at time of funding.**

D. NIH-Format Data and 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, including details such as whether a single person, multiple people, or a data safety monitoring board will provide monitoring and what type indicate what type of entity will provide the monitoring (e.g., PD/PI, Independent Safety Monitor/Designated Medical Monitor, Independent Monitoring Committee, Safety Monitoring Committee, Data and Safety Monitoring

- Board, etc.)
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

II. Instructions for projects involving foreign component

A. Definition of Foreign Component

"Foreign component" is defined as significant scientific activity that was performed outside of the United States, either by the grantee or by a researcher employed by a foreign organization, **whether or not** grant funds were expended. The following grant-related activities are significant and must be reported:

- involvement of human subjects or research with live vertebrate animals;
- extensive foreign travel by awardee project staff to collect data, or conduct surveys or sampling activities; or
- any awardee activity that may have an impact on U.S. foreign policy.

Examples of other award-related activities that may be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.