The Maternal And Developmental Risks from Environmental and Social Stressors Center of Excellence on Environmental Health Disparities Research (MADRES, madres.usc.edu) is pleased to announce its Pilot Projects Program, supporting one-year research projects that aim to address scientific gaps in our understanding of the unequal burden of adverse environmental health impacts in susceptible communities. The goal of the program is to advance environmental health disparities research while also increasing representation of members of health disparity populations in scientific and community-based research.

The MADRES Center is seeking investigator-initiated applications from all environmental health disparities research areas. Pilot project proposals are not meant to fund work in MADRES. Proposals related to disparities in the following topics are particularly encouraged:

- Obesity and cardiovascular diseases
- Mental health
- Maternal and child health
- Immigrant health
- Environmental pollutants
- Acute and chronic stressors
- Environmental exposure mixtures
- Neighborhood-level exposures
- Structural racism, acculturation and environmental justice

ELIGIBILITY

Individuals with a postdoctoral or full-time faculty appointment in any department or school/division at USC or CSUN who are (1) NIH early stage investigators and (2) self-identified members of an NIH-designated health disparity population are eligible to apply. Postdoctoral applicants are required to have a full-time faculty member as a faculty sponsor on their application.

NIH-designated health disparity populations include: Black or African American, Hispanic or Latinx, American Indian or Alaska Native, Asian American, Native Hawaiian or other Pacific Islander, socioeconomically- disadvantaged, underserved rural population, and sexual and gender minorities.

PROPOSAL GUIDELINES

Each application will be required to include the major components of an NIH R03 grant application. In addition, applicants will be required to: (1) describe how a successful pilot project and/or expansion of the project will lead to an R01 or equivalent submission, (2) provide a plan for disseminating research results with consultation from the MADRES Community Engagement & Dissemination Core, and (3) provide evidence that the applicant meets the eligibility criteria.

Instructions for full proposal submission can be found on the MADRES Pilot Projects Program webpage. All proposed projects should have a clear and identifiable environmental health disparities emphasis. Please email full applications as one PDF file to Zoe Birnhak, birnhak@usc.edu by the full proposal deadline.

Key Program Dates

<table>
<thead>
<tr>
<th>Request for Applications</th>
<th>Full Proposal Deadline</th>
<th>Award Notification</th>
<th>IRB Submission Date</th>
<th>NIMHD Submission Date</th>
<th>Award Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 25th, 2022</td>
<td>Sept 12, 2022 at 5:00 pm PT</td>
<td>Nov 2022</td>
<td>Dec 2022</td>
<td>Feb 1, 2023</td>
<td>Apr 1, 2023</td>
</tr>
</tbody>
</table>

The MADRES Center is funded by the National Institute on Minority Health and Health Disparities (NIMHD) and National Institute of Environmental Health Sciences (NIEHS), grant #P50MD015705-06
FULL APPLICATION INSTRUCTIONS

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. A proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the 12-month period of performance.

5. **Budget** – A 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.]

6. **Budget Justification** – A detailed explanation and justification of the funding request.
   *Non-allowable expenses:*
   i. Salaries for co-investigators whom are Associate and Full Professors
   ii. Salaries for co-investigators outside of USC/CSUN
   iii. Tuition for graduate students

7. **NIH-Format Biosketches** – For the PI, co-investigators and faculty sponsors (5 page limit per investigator).

8. **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, co-investigators and faculty sponsors (CITI Human Subjects Training)
   d. If clinical trial, a data safety monitoring plan is also required

9. **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.

10. **Plan for Disseminating Research Results (1 page)**— Applicants are encouraged to consult with the [MADRES Community Engagement & Dissemination Core (CEDC)](http://madrescenter.usc.edu) in developing plans to disseminate pilot project results to target audiences.

    Applicants are advised to contact CEDC Director Jill Johnston, Ph.D. ([jillj@usc.edu](mailto:jillj@usc.edu)).
11. **Program Eligibility (1 page)** – A statement establishing that the applicant meets all of the following eligibility criteria:

A. Postdoctoral or faculty appointment at the University of Southern California or California State University, Northridge

B. NIH Early Stage Investigator (ESI)
   NIH defines an Early Stage Investigator as the following:
   *An investigator who has completed their terminal research degree or end of postgraduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.*

   Investigators still retain their ESI status if they have received any of the following grants from NIH: [https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm](https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm)

C. Self-identified member of an NIH-designated health disparity population:
   - Blacks or African Americans;
   - American Indians or Alaska Natives;
   - Asian Americans;
   - Hispanics or Latinos;
   - Native Hawaiians and other Pacific Islanders;
   - Socioeconomically disadvantaged populations;
   - Underserved rural populations; and
   - Sexual and gender minorities.

   NIH defines sexual and gender minorities as the following:
   *SGM populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.*

**REPORTING REQUIREMENT**

The anticipated period of funded project performance will be April 1, 2023 through March 31, 2024. 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.** All funded projects, along with IRB approval, must be reviewed and approved by NIMHD 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 MADRES Center meeting.

**All publications resulting from pilot funding must include the following acknowledgement:**
*“This work was supported by the MADRES Center of Excellence on Environmental Health Disparities Research, NIMHD grant #P50MD015705.”*
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, 2023.

The major review criteria are:
1. Relevance and potential to identify solutions to environmental health disparities problems;
2. Meets at least two of the NIMHD research framework domains of influence;
3. Displays scientific quality and innovation;
4. Stimulates interdisciplinary activity, particularly with other centers, initiatives, or programs within USC;
5. Focus on health disparities; and
6. Likelihood of leading to R01 or other external funding.

For questions or more information, contact:

Zoe Birnhak, birnhak@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, characteristics and design
   b. Study procedures, materials and potential risks
2. Adequacy of Protection Against Risks
   a. Informed consent and assent
   b. Protections against risk
   c. Vulnerable subjects, if relevant to your study
3. Potential Benefits of Proposed Research to Research Participants and Others
   a. Discuss potential benefits of the research to participants and others
   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.

3. 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).

4. 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. Also 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