



## Call for Pilot Project Proposals

2024 - 2025

OSU COBRE NIGMS P20GM109097

### ANNOUNCEMENT

The Center for Integrative Research on Childhood Adversity ([CIRCA](#)), an NIH Center of Biomedical Research Excellence ([CoBRE](#)), is designed to create a research infrastructure to expand knowledge on the effects of early stress and trauma leading to the development of evidence-based programs and interventions to address the high rate of adverse childhood experiences (ACEs) within Oklahoma and abroad. It is anticipated that by 2027 CIRCA will have invested approximately \$20 million in the development of faculty investigators, expanding core capability and expertise, and strengthening university research infrastructure in Oklahoma.

CIRCA is pleased to announce a call for pilot research proposals to expand and enhance the [scientific goals](#) of the Center. Pilot projects will be awarded for up to **2 years**, have a budget up to **\$100,000** in direct costs, and have an estimated start date of **July 1, 2025** (pending NIH approval).

### PILOT PROJECT GOALS

The purpose of the CIRCA pilot project program is to allow researchers in the field of childhood trauma, adversity, and resilience to compete for 24-month pilot funds needed to prepare for federal independent funding. The CIRCA pilot project program provides funding, research infrastructure, and mentoring to pilot project leaders (PPLs) to support their development to independent federal research status (R01 or equivalent). PPLs are expected to participate in all Center activities, attend meetings, and provide regular project updates to Center and advisory members.

Applicant proposals must align with the central focus of [CIRCA](#), which is to develop and apply knowledge to reduce the effects of trauma and stress in children and families by:

- **Exploring the biological, cognitive, and socioemotional effects of childhood adversity**
- **Developing effective intervention and prevention programs**

The following CIRCA cores is available and we strongly encourage potential PPLs to identify plans to utilize core expertise in their pilot proposal:

**Admin Core:**

Core Director: Dr. Jennifer Hays-Grudo

Core Resources:

- Research mentorship
- Consultation on core utilization
- Budget planning and justifications
- Research team composition and management
- Progress reporting

**RECA Core (Recruitment, Engagement, Collection, Analysis):**

Core Director: Dr. Amanda Morris

Core Resources:

- Recruitment population planning and marketing
- Remote data collection expertise and resources
- Community engagement with partner agencies
- Qualitative and quantitative data planning, collection, and analyses
- CIRCA database

**Biological Systems Core:**

Co-Core Directors: Drs. Kent Teague, Kyle Simmons & Julie Croff

Core Resources:

- Access to biorepository (linked to data variables in REDCap) and variables related to research on stress, adversity, and resilience
- Access to biological assays – (epigenetics, protein assays, RNAseq, methylation)
- Specialized lab tech support and training to operate equipment
- Consultation on data architecture (i.e., data preparation, curation, analysis)
- Remote data collection, including wearable biometric monitoring devices (e.g., Oura rings, Empatica EmbracePlus watches) and biological collection devices (e.g., Mitra, Tasso, dried blood spots)

**ELIGIBILITY**

The Pilot project program aims to assist faculty, particularly early-stage investigators, who have good research ideas but lack the necessary resources to implement the project. The applicant must hold a tenure-track faculty appointment (or equivalent at research institutes). The PPL may not have nor previously had an R01 award. Applications cannot be accepted from faculty who are funded by another CoBRE.

## TIMELINE

Call released	September 20, 2024
Due date of one page pilot proposal summary	October 21, 2024
Full pilot proposal submission deadline	December 16, 2024
Review period (Center & Advisory)	February 1, 2025
Final proposal with revisions (if necessary)	March 1, 2025
NIH approval	June 1, 2025
Anticipated project start date (pending NIH review)	July 1, 2025

## ONE PAGE SUMMARY

To inform the selection of reviewers for pilot proposals, investigators who intend to submit a full pilot proposal in response to this call should compose and submit a one-page summary [via the CIRCA website](#) on or before October 21, 2024. The one-page summary should include a brief description of the aims, design/methods, and how the research aligns with the theme of CIRCA. In addition to the one-page summary, please also include the principle investigator's cv or NIH biosketch. Receipt of the one-page summary and cv/biosketch by the deadline is a prerequisite to submit a full pilot project proposal.

## PROPOSAL REQUIREMENTS

Proposals must be typed, single-spaced with minimum of 1" margins at top, bottom and sides, and using a font no less than 11 point, and must not exceed the page limitations as indicated below. All final proposal documents must be combined into one PDF file for submission.

- Please use [PHS398 forms](#) and [Instructions](#), but only the following sections have to be submitted per [NOT-GM-14-111](#).
  - Face Page* (Page 1):
    - Use appropriate form for [Single](#) or [Multiple](#) PI/PDs
  - Project Summary* (Page 2) (<250 words):
    - [Project Summary form](#)
  - Research Strategy* (limit 5 pages) of the Research Plan section:
    - In the research proposal, please include a description of how your project will utilize the CIRCA Cores (Admin, Biological Systems, Remote Data Collection, Community Engagement).
    - The plan for developing an R01 or equivalent independent NIH proposal upon completion of pilot project.
    - For previous CIRCA Pilot Project awardees, one additional page for the progress report must be submitted that includes progress to date, publications/abstracts/presentations and grants awarded or obtained due to previous CIRCA funding
    - References (limited to one additional page)

2. Provide evidence of Institutional Review Board (IRB) approval.
  - IRB approval may be submitted after proposal submission only with the prior approval of CIRCA PI/PD Dr. Hays-Grudo.
  - NIGMS will not formally approve nor can pilot projects begin until IRB approval is provided to CIRCA.
3. Complete the [Detailed Budget for Initial Budget Period](#) (Page 4).
  - Budgets should include applicable F&A for the investigator.
  - Depending on the investigator's institution and F&A rate, the total estimated pilot cost should not exceed \$100,000 in direct costs for a 24 month grant period.
4. Budget [Justification](#) (Page 5 - Limit 1 page)
  - Please include annual direct costs and calendar effort levels for the project.
5. PHS Human Subjects and Clinical Trials
  - [Human Subjects and Clinical Trials Information Form | grants.nih.gov](#)
6. Evidence of relevant human subjects training education certifications ([CITI](#))
  - Include PDF completion certificate: **Social and Behavioral Research**
  - If proposing clinical trials ([policy](#)), also must include completion certificate: **Good Clinical Practice – Clinical Trials with Investigational Drugs and Medical Devices** ([NIH website](#); [CITI link](#))
7. If the proposal involves **Vertebrate Animals**, follow the new instructions [HERE](#). (no page limit)
8. Biosketch of all [senior/key personnel](#) and [other significant contributors \(OSC\)](#):
  - Use new NIH format for [biosketch form \(non-fellowship\)](#) with a list of current, pending and completed grants.
    - Please include annual direct costs and effort levels (calendar months) for all of the research projects.
  - [Here](#) are some example of non-fellowship biosketches.
  - [This link](#) provides instructions.
9. A letter of support from the investigator's Department Head/Chair
10. Inclusion and affirmation of the following statements by handwritten or electronic signature and date:
  - **I affirm** my understanding of CIRCA as a NIH Phase 2 COBRE with the ability to provide 24-month pilot funding to approved applicants. I understand that an approved CIRCA pilot research project is *different* from the federal, competitive, independent, peer-reviewed grant application process triggered by funding opportunity announcements (FOA). More information on the basics of NIH grants can be found [here](#).
  - **I affirm** that I will communicate to NIH and CIRCA any changes in IRB approval status, start/completion of participant enrollment, study changes, or unexpected adverse events.

- **I affirm** that research will comply with local, state, and federal laws and policies relevant to the proposed interventional study and for reporting adverse events and other information as required to other regulatory agencies (in addition to their stated commitment to reporting as necessary to NIH, CIRCA, and the local IRB).
- **I affirm** that I will include the Data Safety Monitoring Plan (DSMP)/Data Safety Monitoring Board (DSMB) summary in the appropriate section of the CIRCA's Biennial Pilot Project Progress Report.
- **I affirm** that I will acknowledge CIRCA grant support as well as specific Core support (if applicable) in each publication, presentation, press release, or any other written document or electronic format regarding my CIRCA funded research.
  - A disclaimer should be included stating: ***"Research reported in this publication was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number P20GM109097. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."***
  - Prior to issuing any internal or external press release or general communication stated above concerning the activity or outcome of this research, CIRCA PI/PD Dr. Jennifer Hays-Grudo and/or designee must review in advance to allow for coordination and review with NIH awarding IC.

## PROPOSAL REVIEW

At this time, CIRCA will select Pilot Project award recipients (depending on availability of funds) for final approval by the External Advisory Committee (EAC) and NIGMS up to **\$100,000** in direct costs. The proposals will be screened by CIRCA PI/PD (Dr. Jennifer Hays-Grudo) and CIRCA Core Directors, reviewed and evaluated by the EAC, and approved by the EAC and NIGMS based on their:

- Alignment with the purpose of the COBRE grant, focus on subjects related to the underlying causal mechanisms linking poverty, abuse, neglect, family dysfunction, ethnic/racial discrimination or marginalization, or other forms of early life adversity with health and developmental disparities, and/or treatment or prevention programs addressing these issues (e.g., [Protective and Compensatory Experiences \(PACEs\)](#));
- Use of CIRCA Cores, including the Administrative Core, the RECA Core, and the Biological Systems Core (any questions about potential uses or expertise of the cores are welcome);
- Merit of the research design and qualifications of the investigator(s) to successfully implement the research plan described; and
- PI's productivity and potential for successful future funding by NIH (or comparable appropriate funding source).



## REPORTING

- Following the actual pilot start date (NIGMS approval date), awardees must submit a progress report to the Admin Core at CIRCA every six months. The Pilot Project Progress Report is an online tool to manage pilot research progress and will be provided to approved pilots approaching the due dates. Some types of information requested includes the following:
  - A. Brief summary of six-month accomplishments
  - B. Progress on pilot research aims
  - C. Unanticipated issues and resolutions
  - D. Budget status
  - E. Goals for next six months
  - F. List all accepted and published research publications, presentations, posters, and other forms of accomplishment wholly or partially supported by CIRCA pilot project funding
  - G. List of all grants submitted, amounts received during reporting year (May 1 – April 30) and total, grant number, length of grant award (years) *thus far*
  - H. For human subjects research, update data on the [Human Subjects and Clinical Trials Form](#).
- At the conclusion of selected pilot project research or 24 months after specified start date (whichever comes first), awardees will have up to 90 days to complete the final online progress report. Below is an example of the types of information collected in the final pilot progress report.
  - A. List of the major accomplishments of the Pilot Project
  - B. Planned next steps stemming from the Pilot Project
  - C. List all accepted and published research publications, presentations, posters, and other forms of accomplishment wholly or partially supported by CIRCA pilot project funding
  - D. List of all grants submitted and amounts received during reporting year (May 1 – April 30) and total, grant number, length of grant award (years)
  - E. For human subjects research, update data on the [Human Subjects and Clinical Trials Form](#).

For more general information on NIH grant applications and process, please visit [HERE](#).

You are encouraged to contact [Dr. Jennifer Hays-Grudo](#), Principal Investigator/Project Director of CIRCA, before submitting a proposal with questions or for more detailed information.