



# Center for Clinical and Translational Research

UNIVERSITY OF SOUTH CAROLINA

## 2025 CLINTRUSC PILOT AND DEVELOPMENTAL RESEARCH PROJECT PROGRAM NOTICE OF FUNDING OPPORTUNITY (NOFO)

**\*\*\*PRE-APPLICATION REQUIRED\*\*\***

The University of South Carolina's Center for Clinical and Translational Research (ClinTrUSC) solicits applications for the Pilot and Developmental (P&D) Research Project Program.

[Center for Clinical and Translational Research - School of Medicine Columbia | University of South Carolina](#)

P&D proposals should:

1. Advance Clinical and Translational Research
2. Focus on health conditions that affect populations in the Midlands of South Carolina

### **Important General Considerations:**

The P&D Project Program aims to foster translational research that directly addresses pressing health-related issues affecting individuals in the Midlands region of South Carolina. These projects are specifically designed to generate solutions to the region's most significant health challenges. By focusing on conditions prevalent in this region, the P&D Program seeks to create impactful research that will improve health outcomes for these communities. The P&D Program encourages collaboration across disciplines, ensuring that research efforts are not only innovative but also closely aligned with the clinical needs and public health priorities of the Midlands.

P&D projects are aimed at generating preliminary data and results that will be essential for securing subsequent external funding. These projects are expected to produce robust, pilot-level findings that can serve as a foundation for larger-scale grant proposals, such as NIH R01 or U01 applications.

The evaluation of P&D project proposals will place significant emphasis on these criteria: the potential for the research to generate meaningful preliminary data and the likelihood that this data will support successful applications for external funding.

Midlands Region: <https://acrobat.adobe.com/id/urn:aaid:sc:va6c2:24429a4e-f9be-4633-8154-b91a50bfbfe3>

### **Important Dates:**

1. Deadline for submission of pre-application: 5:00 pm on October 1, 2024
2. Deadline for submission of full application: 5:00 pm on November 5, 2024
3. Release of reviews: December 17, 2024
4. Expected project start date: February 4, 2025

### **Award Type and Amounts:**

- **Pilot Projects** are 1-year feasibility projects (maximal budget of \$100,000) to allow investigators to test ideas suitable for development into independent applications such as career development awards (i.e. K awards) or small research project grant awards (i.e. R03 or R21). Indirect costs are not allowed.
- **Developmental Projects** include 1- or 2-year projects (maximal budget of \$200,000 divided into two 1-year budgets up to \$100,000 each). Developmental projects are suitable for the generation of pilot projects to support subsequent investigator-initiated applications such as NIH R01 grants or U01s. Indirect costs are not allowed.

### **Number of awards per cycle:**

The number of awards in each category is contingent on the quality of the applications and available funding.

### **Eligibility:**

1. Individuals holding a faculty position at research institutions dedicated to higher education in South Carolina can lead Pilot and Developmental Projects.
2. All applications must include at least a co-investigator from the University of South Carolina.
3. All applications must include a collaborator affiliated with a clinical facility in the broad Midlands of South Carolina (the "clinical collaborator"). Please note a link above and in our website for a description of the regional locations that qualify as the broad Midlands of South Carolina.
4. Clinical fellows can lead Pilot Projects, which are suitable for development into NIH career projects (K-series). However, they are expected to work with a research mentor when leading these projects.

### **Restrictions:**

1. Funds cannot be used for graduate student or postdoctoral stipends, but students and postdocs may receive salary support as research staff from an awarded project. More specifically, although the grant cannot be used for stipends, it allows for students and postdocs to be compensated if they are hired as research staff. This means they can receive a salary for work performed on the project, but not a stipend which is usually tied to their academic or training status.
2. Postdoctoral scholars and others holding non-independent positions are not eligible to lead any Health Research Core projects, except clinical fellows, who may lead Pilot Projects.
3. Projects may not overlap with ongoing funded projects of the project leads.
4. Health Research Core project leads may not receive simultaneous research support as project leads from this and from another IDeA parent award (e.g., COBRE, INBRE, IDeA-CTR, CTR-N, or CTR-D), but may be eligible to serve as a project lead of a supplement to an IDeA award.
5. Health Research Core project leads, and co-investigators can receive concurrent research support from other NIH support or other sources not listed above.

**Only one proposal per funding period will be accepted from any faculty.**

### **Responsiveness:**

We will consider proposals to be responsive to this call if they:

1. Address any topic covered within the broad scope of the NIH or other funding agencies. That is, there is no restriction as to outcomes, risk factors, or other factors;
2. Focus on a problem in public health or clinical medicine that is evident in our geographical region;
3. Describe a realistic path toward obtaining extramural research funding within 1-3 years.

Proposals that are highly innovative and address a serious health disparity within ClinTrUSC's catchment area will be given special consideration.

### **Proposal Preparation Instructions:**

All documents must be completed according to the NIH guidelines for "R" series awards. Proposals must be prepared with 0.5" margins all around, using Arial (or similar sans serif font; font size no smaller than 11 pt). The application forms package can be accessed via REDCap (links included below).

#### **NIH Required Documents.**

- **Face Page.** This page must be filled out in its entirety and signed by an authorized institutional representative.
- **Biographical Sketch of Project Lead and Investigators.** (NIH-format)
- **Biographical Sketch of the Mentor (if applicable).** (NIH format)
- **Updated Other Support.** Project Lead and Investigators
- **Updated Other Support.** Mentor (if applicable)
- **Project Summary.** 30-line limit

- **Detailed Budget and Justification.** Salary is allowed for the Project Lead and Co-Investigators.
- **Specific Aims.** 1 page
- **Research Strategy.** Provide a description of the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of the project, and a description of the experimental design and methods proposed and how the investigator will achieve robust and unbiased results. Up to 3 pages for Pilot Projects and up to 6 pages for Developmental Projects.
- **Bibliography.**
- **Authentication of Key Biological/Chemical Resources.** Describe methods/procedures for validating the identity of significant biological/chemical agents used (if applicable).
- **Human Subjects.** If research involves human subjects, include PHS Human Subjects and Clinical Trials Information Form. Prior to approval of funding by NIH, Human Subjects Education Certification and Institutional Review Board (IRB) approval are required.
- **Clinical Trials.** In addition to Human Subjects requirements above, if the proposed project involves clinical trials include Documentation of Investigational New Drug (IND)/Investigational Device Exemption (IDE) status for studies that are subject to FDA regulation, and Human Subjects Education Certification and Good Clinical Practice (GCP) Training Certification. Refer to the NIH's Definition of a Clinical Trial and use <https://grants.nih.gov/ct-decision/index.htm>.
- **Vertebrate Animals.** If the project involves vertebrate animals, provide the Vertebrate Animals Section (see <https://olaw.nih.gov/guidance/vertebrate-animal-section.htm> for additional information). Prior to approval of funding by NIH, IACUC approval is required.
- **Checklist:** This page must be filled out in its entirety. Indirect costs are not allowed.

#### **Additional ClinTrUSC Required Documents**

- **Biosafety.** Discuss the biosafety aspects of the proposed work and, if necessary, file for approval from the Institutional Biosafety Committee.
- **Data Sharing Plan.** Describe the plan, consistent with NIH data/resource sharing policies (<https://grants.nih.gov/policy/sharing.htm>), for sharing of research data/resources generated.
- **Plans for Core Usage:** State plans for participation in the Professional Development (PD) Core, the Community Engagement and Outreach (CEO) Core, and the Research Design, Compliance, and Data Management (RCDC) Core. Usage of other ClinTrUSC affiliated cores can also be included (see list below). Applicants can request a \$5,000 voucher for use of ClinTrUSC affiliated cores. This should be requested in the plans for core usage document. Do not include in the budget.
- **Plans for Dissemination of Findings and Grant Submissions.** Describe plans for publication and plans for submission of external grant applications.
- **Letter of support from Clinical Collaborator.** There is a \$2,500 supplement available for the clinical collaborator. Do not include in the budget.
- **Letter of support from Mentor (if applicable).** There is a \$2,500 supplement available for the Mentor. Do not include in the budget.

#### **Utilization of Core Facilities**

P&D project applicants can propose to work with one or more of the ClinTrUSC Cores (see below). P&D project awardees will have priority access to these cores. Cores affiliated with the NIGMS funded Center for Targeted Therapeutics (CTT) and Center for Dietary Supplements and Inflammation (CDSI) are also available to P&D project applicants (note: priority access will be given to faculty associated with those centers). The School of Medicine Instrumentation and Resource Facility is available to all P&D project applicants.

- **ClinTrUSC Health Research (HR) Core**  
Dr. Leonardo Bonilha (clintruscHRcore@uscmed.sc.edu)  
Dr. Angela Murphy (clintruscHRcore@uscmed.sc.edu)
- **ClinTrUSC Professional Development (PD) Core**  
Dr. Lorne Hofseth, College of Pharmacy (hofseth@cop.sc.edu)

- **ClinTrUSC Community Engagement and Outreach (CEO) Core**  
Dr. James Hebert, Arnold School of Public Health (jhebert@mailbox.sc.edu)
- **ClinTrUSC Research Design, Compliance, and Data Management (RDCD) Core**  
Dr. JiaJia Zhang, Arnold School of Public Health (jzhang@mailbox.sc.edu)
- **Center for Targeted Therapeutics, Functional Genomics Core**  
Dr. Michael Shtutman, College of Pharmacy (shtutmanm@cop.sc.edu)
- **Center for Targeted Therapeutics, Drug Design and Synthesis Core**  
Dr. Campbell McInnes, College of Pharmacy (mcinnes@cop.sc.edu)
- **Center for Targeted Therapeutics, Microscopy and Flow Cytometry**  
Dr. Chan-uk Lim (Flow Cytometry), College of Pharmacy (limc@cop.sc.edu)  
Dr. Vitali Sikirzhytski (Microscopy), College of Pharmacy (sikirzhy@mailbox.sc.edu)
- **Center for Dietary Supplements and Inflammation, Bioanalytical Core**  
Dr. Xiaoming Yang, School of Medicine (Xiaoming.Yang@uscmed.sc.edu)
- **Center for Dietary Supplements and Inflammation, Flow Cytometry, Microscopy and Imaging Core**  
Dr. Narendra Singh, School of Medicine (Narendra.Singh@uscmed.sc.edu)
- **School of Medicine & Office of the Vice President for Research Instrumentation Resource Facility**  
Dr. Austin Worden, School of Medicine (Austin.Worden@uscmed.sc.edu)
- **School of Medicine & Office of the Vice President for Research Healthcare Evaluation Systems and Technological Informatics Archive (HESTIA)**  
Dr. Austin Worden, School of Medicine (Austin.Worden@uscmed.sc.edu)

## Review

The Administrative Core and Health Research Core personnel will review applications to determine responsiveness to the NOFO, eligibility of the applicant, completeness of the application, and information regarding human subjects and vertebrate animals. Applications deemed incomplete, ineligible, or not responsive will be returned to the applicants.

All proposals that meet the eligibility requirements and guidelines will be independently evaluated by ClinTrUSC's Scientific Review Committee. Reviewers will apply the following review criteria:

- Scientific merit of the proposed project as evidenced in the significance, innovation, and approach section of the proposal.
- Potential to lead to a competitive extramural grant proposal focused on clinical and translational research.
- Potential for publication.
- Qualifications of the Project Lead.
- Consistency with responsiveness criteria.
- Qualifications of Clinical Collaborator(s) and Mentor(s) (if applicable).
- Utilization of ClinTrUSC cores.
- Focus on health conditions that affect populations in the Midlands of South Carolina

Final decisions on funding will be made by:

1. ClinTrUSC's Steering Committee
2. The NIH

## Awards and Reporting Requirements

All applicants will receive a notice of award/declination and copies of the reviewers' comments via email. Award recipients are required to provide the ClinTrUSC Administrative Core with project data for evaluation and reporting purposes, as follows:

1. Award recipients will be contacted quarterly to request updates on the supported activity, summary of expenditures, and any project achievements to date (publications, presentations, proposals submitted/funded, new collaborations, new appointments, honors or awards, and citations). P&D award

recipients are expected to publish their results and present them at regional and/or national conferences. Awardees are also expected to apply for extramural support as soon as possible during or after the completion of their P&D award work.

2. A comprehensive final report is due 30 days after the end date of the award.
3. All publications, resulting even in part from work supported by ClinTrUSC, must acknowledge ClinTrUSC support and a PMCID must be obtained for each publication in a timely fashion. PMCID information must be provided to the ClinTrUSC administrative staff as soon as available.

After the expiration date of each award, ClinTrUSC will continue to contact awardees for outcome-related data such as grants, publications, etc. All publications emanating from P&D Projects must acknowledge CLINTRUSC funding (P20 GM155896). Failure to provide any requested materials for award or evaluation purposes will constitute default under this program and disqualify the P&D recipient from further ClinTrUSC support.

### **Application Submission Instructions and Contact Information**

The pre-application must be submitted via REDCap by 5:00 pm on October 1, 2024. It should include the title, names, and affiliations of investigators, and a short description of the project (limited to 300 words).

[https://redcap.link/CLINTRUSC\\_PreApplication](https://redcap.link/CLINTRUSC_PreApplication)

Full applications, including required signatures on the Face page, must be submitted via REDCap no later than 5:00 pm on the deadline November 5, 2024.

[https://redcap.link/CLINTRUSC\\_Application](https://redcap.link/CLINTRUSC_Application)

If you have any questions relating to this NOFO please contact:

Dr. Leonardo Bonilha or Dr. Angela Murphy [clintruscHRcore@uscmcd.edu](mailto:clintruscHRcore@uscmcd.edu)