Clinical and Translational Science Institute (CTSI)
Biostatistics, Epidemiology, and Research Design (BERD) Program
Request for Applications for Statistical/Novel Methods Pilot Awards

Purpose

The CTSI Biostatistics, Epidemiology, and Research Design (BERD) Program is seeking applications for pilot funding for projects which would lead to a publication describing a methodological development.

The goal of this request is to encourage development of new methodology, defined very broadly. Examples include, but are not limited to, development of a new statistical technique to analyze a particular kind of data, qualitative methods (e.g., refined cognitive interviews), research designs, techniques for analyzing large data, and novel technologies (e.g., mobile data collection, eye-tracking, virtual reality-based assessments). The scope of this RFA also includes the novel application of existing methods into a new area of research.

Successful proposals will lay out a reasonable project plan that is feasible to complete in the 12-month project period as there will be no opportunity to request carryover.

No pilot data are necessary to apply for this RFA, however supporting data from the recent literature are appropriate if available.

Funding

Up to two projects will be funded. Successful pilots will receive up to **$10,000** each, to be spent within a **12-month project period.** All projects must meet the above specifications outlined under "Purpose."

Project final budgets will be based on a complete review of the budget and budget justification. See "Budget Guidelines" below for more details. All funds are to be spent within a one-year project period; due to the restrictions on CTSA funding, no-cost extensions cannot be approved.

Eligibility

These awards are open to all faculty with a rank of instructor of higher across the Atrium Health Enterprise including Atrium Health, Atrium Health Navicent, and Atrium Health Wake Forest Baptist, including Wake Forest School of Medicine. Wake Forest University faculty and all CTSI affiliated institutions with a Wake Forest co-investigator are also invited to apply.

Additional Information:

- More than one proposal may be submitted per faculty member serving as PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle.
- CTSI KL2 scholars whose KL2 funding is active during the pilot project period are not eligible to apply.
- Projects that have been previously funded (or projects with very similar ideas) will not be considered.
- Investigators with active Ignition Funds remain eligible.

Key Dates

Date	Detail
03/18/2022, 11:59 pm	Full Application Deadline
04/15/2022	Selection of Awardees
06/01/2022	If applicable, completed materials sent to NCATS for approval (Appendix I)
07/01/2022	Project Start Date
06/30/2023	Project End Date

CTSI Resources Available to Support Investigators

Several resources are available in the CTSI to help submit a strong application; while they are not required as part of the submission, investigators are highly encouraged to seek out additional assistance. All services can be requested through the CTSI Service Request form.

- **Grant Proposal Editing:** have an expert medical editor review your proposal prior to submission. She will offer suggestions on how to refine your writing and thinking. Your proposal will be edited in "track changes" so that you can easily accept or reject edits (free to everyone).

- **Research Studio:** meet with a multi-disciplinary panel of experts to work through specific aims, hypotheses, or ways to address the generalizable requirement (free to everyone).
- **Informatics:** optimization of the EMR to extract data for research purposes (free or fee-for-service, depending on need).

Application Procedure

Full Application Deadline: 03/18/2022, 11:59 pm
The full application should be submitted through the ePilot electronic submission system by **03/18/22.** **Applications received after 03/18/22 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

Applications that do not comply with these guidelines will not be considered for review.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information

- Project Title
- Submitting Principal Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max)

Research Strategy (6 pages max, all items below are required components)

- Specific Aims
- Research Plan:
  - Significance
  - Innovation
  - Approach
  - Study Team
- Study milestones and anticipated outcomes (e.g., publication, presentation, grant submission, patent) with timeline (see Appendix II for examples)

References (no page limit)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- IRB Approval Status (please note: IRB approval is not required for full application submission)
- Clinical Trial Classification Questions
  - If your project requires an IND/IDE submission or exemption, please consult with Issis Kelly Pumarol at ikellypu@wakehealth.edu for support and to discussion timelines. The timelines can impact your full project timeline and should be considered in the project plans.
- Protection of Human Subjects
  - Needs to clearly describe risk, protections, benefits, and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
- Inclusion Across the Lifespan
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Recruitment and Retention Plan
- Targeted Enrollment Table (using NIH Targeted Enrollment Table)
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable

- If you are unsure how much safety monitoring your study will need, please contact the CTSI DSMB Administrator, Issis Kelly Pumarol, at ikellypu@wakehealth.edu.

Information Regarding Live Vertebrates
Address the following if the project **involves live vertebrates**.

- IACUC Approval Status (please note: IACUC approval is not required for full application submission)
- IACUC approval will be required (as 'just in time' information) for implementation of projects with live vertebrate animals

Budget and Justification (**budget template plus 1 page justification**)

- Complete the budget template form and a brief justification for the funds requested. Please explain how other resources may be leveraged to support the project. If the proposed research will be done on more than one campus/institution, please include details in the justification.
- Sub-awards to other institutions to carry out work on a project are not allowed.
- Through the BERD Program, Drs. Edward Ip and Sean Simpson are available for consultation regarding methodological development; no budget line item is necessary for this.

NIH-style biographical sketch for all Key Personnel

Review Criteria and Process for Full Proposals
CTSI proposals are competitive and peer reviewed. Proposals will be evaluated by CTSI BERD Leadership and external reviewers based on NIH review criteria and scoring. Final award approval will be at the recommendation of CTSI BERD Leadership.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the CTSI BERD and Translational Pilot Program.

Reviewers will score applications from 1 to 9 based on:

1. Significance of the problem to be addressed
2. Innovation of the proposed solutions
3. Strength and breadth (interdisciplinary nature) of the investigative team
4. Methodological rigor and feasibility, with clear milestones
5. Generalizability: Likelihood the innovation will be broadly applicable and impact translational research or delivery of care
6. A reporting plan, whether the study yields positive or negative results
7. The likelihood that the investment will lead to external funding, publication, or a licensable innovation; early-career faculty involvement, race/gender inclusiveness of the research team; and inclusion of women, minorities, older adults, and children as potential study participants.

Budget Guidelines

The project is one year beginning 07/01/2022 and ending 06/30/2022. Up to $10,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Travel, if necessary to perform the research
- Small equipment, research supplies, and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may not be budgeted for:

- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Capital equipment

- Manuscript preparation and submission
- Indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. The CTSI reserves the right to revoke funding if it is determined that funds were not spent in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects are set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Program Expectations

Prior to funding, awardees will be assigned to a Research Navigator to: 1) assist with study initiation; 2) convene an initial meeting with the project PI, CTSI administrative personnel, and a senior CTSI leader to discuss the project and how CTSI resources can be leveraged for the pilot grant; and 3) monitor progress throughout the life of the study. If any significant issues arise, the study team will be required to work with the CTSI to determine solutions so that the study can be successfully completed (or in rare cases, terminated).

Specific Deliverables

- Participation in the study initiation meeting
- Formal progress reports at 6 and 12 months
- Upon completion of the project:
    - Close-out report, with plans for implementing and disseminating innovations
- Presentation of findings at requested events (i.e., CTSI Seminar Series, Service Line Meeting, CTSI's annual External Advisory Committee meeting)
- Manuscript submitted within one year of the end of the pilot award
- Disclosure of 1) how results will be implemented and/or disseminated; 2) applications for extramural funding beyond the pilot grant; 3) what subsequent notification of funds occurred; and 4) related publications or significant collaborations resulted from the project, for a minimum of 4 years after completion of the award.
- Citing the CTSA grant as a funding source for papers and presentations.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approval from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CTSI prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
2. Research involving human subjects must also have approval from the National Center for Advancing Translational Sciences (NCATS). NCATS has defined human subjects research (HSR) categories and determined the approval procedures per category. NCATS submission will be facilitated by the CTSI. Note: The study cannot be submitted to NCATS until **after** IRB approval has been given.
    a. **Category 1**: Greater Than Minimal Risk studies and all NIH-defined Clinical Trials
        i. Category 1 studies/trials require approval from NCATS to begin.
    b. **Category 2**: Minimal Risk and Exempt Studies
        i. HSR study is exempt and/or considered minimal risk by the IRB
        ii. Category 2 studies must be submitted to NCATS, but do not require formal approval.
3. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the CTSI prior to funds being released.
4. CTSI staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
5. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National

Institutes of Health under Award Number UL1TR001420. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Publications must also be registered in PubMed Central.

6. Any awardee who leaves his or her position should contact the CTSI to discuss plans for the project.

Grant Administration

The Principal Investigator is responsible for the administration of grant funds.

Contacts

Questions about your research project or the ePilot electronic submission system should be directed to Brittney Patterson at britjack@wakehealth.edu.

Appendix I: NCATS Approval

Projects that meet the definition of human subjects research will require prior approval from the National Center for Advancing Translational Sciences (NCATS), the funding source of the CTSA grant. This means that no funds will be released to the award recipient until NCATS has provided approval.

The following items are needed for the NCATS submission by 06/01/22 (if an investigator is not ready to submit to NCATS by 05/07/21, their project timeline <u>will not</u> be altered to accommodate):

- Project Information (i.e., submitting investigator, project title)
- IRB Approval
    - We do not require an initiated IRB application/approval by the Full Application Deadline; however, in order to submit for NCATS approval, certification of IRB approval is required. Therefore, we encourage draft protocols/consent documents be created as far in advance as possible. Notifications of funding will be sent by 04/15/22.
- Project Abstract
- IRB Approved Protocol
- IRB Approved Consent/Assent/waiver
- Protection of Human Subjects
- Inclusion of women, minorities, and children
- Recruitment and Retention Plan
- Targeted Enrollment Table
- Biosketches (PI and Key Personnel)
- Documentation of CITI certification
- Data and Safety Monitoring Plan
- IND/IDE Documentation, if applicable
- Budget and Budget Justification

Please note: additional documentation will be required if project is classified as a Clinical Trial.

Appendix II: Study Milestone Examples

Below are examples of study milestones, outcomes, and timelines. However, these formats are not required.

Example 1:

- **Milestone 1 (0-1.5 months):** Milestone 1 Details **Outcome:** Outcome 1 Details
- **Milestone 2 (1.5-4 months):** Milestone 2 Details **Outcome:** Outcome 2 Details
- **Milestone 3 (4-6 months):** Milestone 3 Details **Outcome**: Outcome 3 Details
- **Milestone 4 (6-12 months):** Milestone 4 Details **Outcome:** Outcome 4 Details
- **Milestone 5 (8-12 months):** Milestone 5 Details **Outcome:** Outcome 5 Details

Example 2:

Timeline and Milestones												
Month	1	2	3	4	5	6	7	8	9	10	11	12
Activity/Aim/Milestone 1	X	X	X	X								
Activity/Aim/Milestone 2	X	X										
Activity/Aim/Milestone 3		X	X	X								
Activity/Aim/Milestone 4					X	X	X	X	X	X		
Activity/Aim/Milestone 5					X							
Activity/Aim/Milestone 6						X	X					
Activity/Aim/Milestone 7								X		X		
Activity/Aim/Milestone 8											X	X

Example 3:

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
1	Milestone 1	X	X		
	Milestone 2		X		

Aim 1 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
2	Milestone 1		X	X	
	Milestone 2		X		
	Milestone 3			X	

Aim 2 Anticipated Outcomes: Detail

Aim	**Milestone**	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**
3	Milestone 1			X	
	Milestone 2			X	X

Aim 3 Anticipated Outcomes: Detail