Clinical and Translational Science Institute (CTSI)
Request for Applications for Pilot Awards Addressing the Opioid Epidemic and Pain Management

Purpose

The purpose of this RFA is to support Wake Forest investigators interested in applying to a funding opportunity under the NIH HEAL (Helping to End Addiction Long-term) Initiative. The CTSA is offering up to two $20,000 (or two $30,000, if informatics-related) 6-month planning or pilot grants to support research that focuses on patient populations, patient or provider behavior change, use of clinical data, analysis of care delivery, or implementation of new clinical care models. Proposals should support competitive applications to treatments or the delivery of care, and therefore should concentrate on translational and clinical research. Basic science proposals will not be responsive to this call for proposals due to new NCAT regulations guiding CTSA spending. Research activities may include but are not limited to: analyzing existing data, conducting community assessments, assessing usual care, pilot testing data collection instruments or procedures, conducting formative research on intervention strategies or messages, testing recruitment or intervention feasibility, and investigator and/or staff effort during the development of an NIH application submitted to the HEAL initiative (e.g. writing, establishing partnerships for a multisite trial).

Awardees are expected to apply for any of the HEAL funding opportunities: https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative/funding-opportunities within a year of completing their CTSA award. No pilot data is necessary to apply for this RFA, however supporting data from the recent literature is appropriate if available. Applicants must clearly describe how the proposed project will support a future application to a funding opportunity under the HEAL initiative.

Funding

Up to 2 projects will be funded. Successful pilots will receive up to **$20,000** in direct costs. All projects must meet the above specifications outlined under "Purpose." **Projects that are informatics related are eligible to receive up to $30,000 in direct cost.**

Project final budgets will be based on a review of the budget and budget justification. All funds are to be spent within the 6-month project period; due to restrictions on CTSA funding, no-cost extensions cannot be approved.

Eligibility

These awards are open to all faculty with a rank of instructor or higher from Wake Forest (Health Sciences & University) and all CTSI-affiliated institutions with a Wake Forest co-investigator.

Additional Information:

- Investigators can apply to other intramural HEAL pilot RFAs as long as work and money does not overlap
  - Allowed: one pilot is used for data collection and another to cover investigator effort during grant development.
  - Not allowed: same research aims/plan supported by two internal sources of funds
- Projects already submitted as CTSI or other intramural Pilot Proposals are eligible, but must incorporate reviewer feedback.
- 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
04/30/19, 11:59 pm	Full Application Deadline
07/01/19	Selection of Awardees
08/15/19	If applicable, completed materials sent to NCATS for approval (Appendix II)
10/01/19	Project Start Date
03/31/20	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, it is highly encouraged to seek out additional assistance. All services can be requested through the CTSI Service Request form.

- **Biostatistical Support:** meet with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission (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).
- **CTSI Faculty Consultation:** meet with a CTSI faculty member (clinician, basic scientist, or behavioral scientist) to talk through project ideas or to find research/clinical partners (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: 04/30/19, 11:59 pm

Investigators can submit their proposal through the ePilot electronic submission system, by the deadline noted above. Application instructions are included in the ePilot system and summarized below.

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 (30 lines of text or less)

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 with timeline (see Appendix I 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
- Protection of Human Subjects (1 page max)
  - 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 Plans for Women, Minorities, and Children, if applicable
- Targeted Enrollment Table, if applicable (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)

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 are permissible, provided that most of the pilot's projects activities and dollars spent occur within Wake Forest or its affiliates (and can be completed within the timeline of the project)

NIH-style biographical sketch for all Key Personnel

Budget Guidelines

The project is one year beginning 10/1/19 and ending 3/31/20. Up to $20,000 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).

Review Criteria and Process

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed.
2. Proposals that pass the Administrative Review are peer-reviewed by the WF Intramural Research Support Committee (IRSC), a Dean-appointed committee of selected expert faculty, using NIH review criteria and scoring. Budgets will be reviewed by both CTSI Administrators and IRSC for appropriateness.
3. Final award approval will be at the recommendation of CTSI Leadership.

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 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.

Preference will be given to projects that: (a) include clinicians as co-Is, or (b) are conducted in routine health care settings.

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
- 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.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB and NCATS. 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. 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.
3. CTSI staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. 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.
4. 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.
5. 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 Lindsay Trost at ltrost@wakehealth.edu.

Appendix I: 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

Appendix II: 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 8/15/19 (if an investigator is not ready to submit to NCATS by 8/15/19, 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 7/1/19.
- Project Abstract
- IRB Approved Protocol
- IRB Approved Consent/Assent/waiver
- Inclusion of women, minorities, and children
- Targeted Enrollment Table
- Recruitment and Retention Plan
- Key Personnel Biosketches
- Documentation of CITI certification
- Data and Safety Monitoring Plan
- If project is classified as a Clinical Trial, additional information will be needed