CTSI Pilot Project Awards
Request for Applications (RFA):

Patient-Oriented Clinical Research

Timeline: 2018-19 Open RFA (applications accepted on a rolling basis)

Applications can be submitted in response to this RFA on any date between April 1, 2018 and March 31, 2019. Successful applicants will have up to 18 months from date of grant award notice to complete their projects.

Nature and Purpose of this RFA

The UF Clinical and Translational Science Institute will provide funds for pilot research projects conceived and designed by translational researchers and clinicians at University of Florida. Success of this program will be judged by the rate at which these grants support the growth of interdisciplinary and investigator-initiated clinical and translational research across UF’s broad range of scientific disciplines. It is expected that all research supported by CTSI Pilot Project Awards will provide critical preliminary data to support extramural applications.

This RFA supports patient-oriented clinical research as defined by the NIH:

“Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.”

Scope of the Patient-Oriented Clinical Research Pilot Program

The CTSI welcomes proposals in response to this RFA for patient-oriented clinical research. Funding decisions will consider the following criteria:

- Meets the NIH definition of patient-oriented clinical research;
- Utilization of CTSI services. The CTSI offers an array of research resources in support of research at UF and we strongly encourage CTSI pilot grant applications to include these valuable resources.
  - Examples:
    - Biorepository
    - Biostatistics
    - Clinical Research Center
    - CTS-IT
The UF CTSI is supported in part by NIH awards UL1TR001427, KL2TR001429 and TL1TR001428.

- HealthStreet
- Integrated Data Repository (IDR)
- Recruitment Center
- Regulatory Support – IRB
- Regulatory Support – IND/IDE

- For a complete list of available resources, please visit the CTSI website at: [www.ctsi.ufl.edu/research](http://www.ctsi.ufl.edu/research). For assistance or initial consultation, contact Holly Morris, Director of Research Services at hlmorris@ufl.edu.

- Performed at a UF or UF Health facility;
- Addresses the inclusion of special populations, including children, the elderly, the medically underserved and/or underrepresented in the targeted enrollment;
- Provides sufficient information to support successful recruitment and retention; including feasibility data (e.g. i2b2 query where appropriate);
- Includes additional funding support from other internal or external sources, for example, departmental or foundation funding is preferred but not required;
- Multidisciplinary, collaborative and/or inter-institutional within the UF clinical and translational research enterprise;
- Encourages the development or use of emerging methodologies and technologies that may affect future research;
- Allows for rapid acquisition of proof-of-principle data to proceed with full-scale investigations;
- Supports the participation of clinical and translational science trainees;
- Shows significant promise in securing external funding;
- Provides insights that could be generalizable to other projects or could lead to the adoption of best practices in the prevention and treatment of disease.

**Eligibility**

- Applicants must be a UF faculty member or a UF trainee (residents, postdocs and fellows) and meet [UF IRB Investigator qualifications](http://www.ufl.edu).
- Applicants can only submit one CTSI pilot application for which they are the principal investigator, but individuals can be listed as co-investigators on more than one proposal in the same funding cycle.
- Recipients of previous CTSI pilot awards are eligible to apply for awards to support fundamentally new research projects, providing awards are at least two years apart.

**Review Process and Criteria**

An initial review of all submitted grant applications will be performed to ensure close alignment with the overall nature and purpose of the RFA, and including application completeness, feasibility, and budget compliance.

Applications that meet all criteria will move forward to undergo scientific and statistical review by the CTSI Scientific Advisory Committee (SAC). Assigned reviewers will score the proposal employing the same criteria used in NIH peer review.
Investigators will receive notice of award or non-award and all applications will receive written critiques.

Final CTSI funding decisions are based on criteria and principles as discussed above. The review process from time of submission to notice of award generally takes 4-6 weeks. Unapproved applicants may not resubmit in the same funding cycle.

Total Available Funding and Award Amounts

The CTSI will make a total of up to $150,000 available through this RFA for the period of April 1, 2018 through March 31, 2019, depending on the quality of submissions and budget availability.

Up to $25,000 may be requested for a period not to exceed 18 months. Projects with larger budgets may be considered based on the scientific merit of the project and if the additional funds are required for project success.

Budget Development

See Instructions for all requirements and details with RFA application. Investigators should develop budgets based on the number of subjects to be enrolled, the cost per subject, and any other services required by the protocol. All budgets will be judged on scientific merit related to the goals of the proposed work.

Applicants should utilize the NIH standard “Detailed Budget for Initial Budget Period” form and the CTSI Budget Justification Worksheet provided in the application. The budget justification worksheet must explain all costs associated with the project. Indicate the funding source for each line item (i.e. department, Gatorade, CTSI, etc.). In addition, CTSI services require cost estimates in writing from CTSI Service providers. For a complete list of available resources, please visit the CTSI website at: www.ctsi.ufl.edu/research

Budgeting and Spending Guidelines

- Funds can only be used for direct costs;
- Majority of line items should be related to clinical research related activities;
- Funds cannot be used to support faculty salaries, student tuition, or other student-related expenses;
- Funds cannot be used for the following: major equipment purchases, desktop or laptop computers, mobile devices, software, licensing fees;
- Funds cannot be used for inpatient bed charges;
- Funds are not provided for conference registration and related travel expenses;
- Funds are non-transferable;
- Funds must be used in the 18-month period following award notification. Any un-spent funds will be returned to the CTSI at the end of the 18-month funding period;
- Funds must be used for the activities detailed in the application and final approved budget;
- Funds requested for CTSI services will be provided as non-transferable credit;
• Continued funding during the award period is contingent on compliance with awardee requirements and adequate progress in meeting the project timeline.

For additional budgeting questions and information, send all inquiries to: CTSIClinicalRFA-L@lists.ufl.edu

Awardee Requirements

• Compliance: Awardees must be in compliance with all IRB policies. Final IRB approval is not required for grant consideration; but applicants are encouraged to begin the submission process early so minimal time will be lost in securing approval. Funds will be made available once final IRB approval is documented and on file with the CTSI.

• Reporting: Awardees must submit recruitment and enrollment reports every 3 months and general progress reports every 6 months after the notice of award. Recruitment and enrollment reports will include enrollment status and inclusion data. General progress reports will include additional fiscal and scientific status information. Awardees are also required to notify the CTSI of any serious adverse events that occur during conduct of the project.

• Dissemination: Awardees are expected to present their research during the annual UF CTSI Research Day in the form of a poster or presentation. Awardees are also expected to present the results of their research at scientific meetings and publish findings in scholarly journals.

• In accordance with NIH requirements:
  o All presentations and publications resulting from work funded by a CTSI Pilot Project Award must include a funding citation. The following language should be used: “Research reported in this publication was supported by the UF Clinical and Translational Science Institute, which is supported in part by the NIH National Center for Advancing Translational Sciences under award number UL1TR001427. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
  o Awardees must ensure that electronic versions of any peer-reviewed manuscripts arising from CTSI-funded research and accepted for publication are deposited in PubMed Central, the NIH's digital archive of biomedical and life sciences journal literature.
  o Awardees must notify the CTSI at CTSIClinicalRFA-L@lists.ufl.edu during the funding period if there is a significant change in the scope of work that would affect the outcome of the project or necessitate re-budgeting.

Application Instructions

Applications must include a cover sheet signed by the principal investigator and the PI’s department chair; page 2 (abstract, translational impact, external funding plan, mentoring plan (if applicable)); research plan; list of key personnel; NIH biosketches for PI, investigator(s) and mentor(s); completed detailed budget for initial budget period, CTSI budget justification worksheet, written cost estimates for CTSI services, and letters of support (if applicable). Proposals that are incomplete or otherwise do not follow instructions will be returned to the investigator without review. Download the application form.
Contact for Questions

Please email questions to CTSIClinicalRFA-L@lists.ufl.edu. Applicants are encouraged to visit www.ctsi.ufl.edu to learn about additional CTSI services available to facilitate research at UF.