CTSI Pilot Project Awards
Request for Applications (RFA):

Patient-Oriented Clinical Research

Timeline: 2016-17 Open RFA (applications accepted on a rolling basis)

Applications can be submitted in response to this RFA any date between April 2016 and March 31, 2017. Successful applicants will have up to 12 months from date of IRB approval to complete their projects.

Purpose

The UF Clinical and Translational Science Institute provides intramural awards to 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.”

The CTSI welcomes proposals in response to this RFA for patient-oriented clinical research utilizing CTSI services performed at a UF Health facility. Both outpatient research and inpatient research may be proposed in response to this RFA. Preference will be given to research conducted at the UF Clinical Research Center, which occupies the first floor in the north wing of the Clinical and Translational Research Building (CTRB):

The UF Clinical Research Center (CRC) supports clinical research involving any disease area or age group. It offers nursing, bionutrition and laboratory services. Facilities in the CTRB include pediatric and adult waiting areas, 14 exam rooms, 8 infusion bays, 2 procedure rooms, an on-site investigational pharmacy and a metabolic kitchen, plus reception, consenting, phlebotomy, sample processing and laboratory areas. It is also equipped with a treadmill, exercise bike, Bod Pod, pulmonary function and pain testing research equipment. On-site parking is available for research participants. The CRC nursing staff can also provide support to inpatient proposals. To request more information about the UF Clinical Research Center, please contact Glenna Paguio, RN, MSN, Nurse Manager (paguig@shands.ufl.edu) or visit http://www.ctsi.ufl.edu/crc.

http://grants.nih.gov/grants/glossary.htm#ClinicalResearch

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Eligibility

- Applicants must be a UF faculty member or a UF trainee (residents, postdocs and fellows) at the time funds are awarded.
- 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.
- 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.

Awardee Requirements

- Awardees must be in compliance with all IRB policies. Applicants whose proposals will require IRB approval should demonstrate they have taken preliminary steps to prepare submissions, so minimal time will be lost in securing approval. Funding cannot be used until appropriate approvals are in place.
- Awardees must submit progress reports every 6 months after the notice of award is received. Reports will include enrollment status and inclusion data, as well as fiscal and scientific status.
- 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:
  - 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.”
  - 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.
  - 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.

Review Process and Criteria

**Scientific Reviews:** Upon passing an initial review, which includes a feasibility, budgetary and biostatistical review, proposals will undergo scientific review at a CTSI Scientific Advisory Committee (SAC) meeting. Applicants may be asked to present their proposals in person to the SAC. SAC reviewers will use NIH review criteria to score submissions based on scientific merit.

**Funding Decisions:** In addition to scientific review scores, the CTSI will consider the following criteria in making its funding decisions, specifically whether proposals:

- Pertain to NIH-defined patient-oriented clinical research;
- Utilize services of the CTSI (a roster of CTSI services and contacts can be found at www.ctsi.ufl.edu/research);
• Address the inclusion of special populations, including children and the elderly, in the targeted enrollment;
• Receive funding support from other internal or external sources, for example, departmental or foundation funding;
• Are multidisciplinary, collaborative and/or inter-institutional in the clinical and translational research enterprise;
• Encourage the development or use of emerging methodologies and technologies that may affect future research;
• Allow rapid acquisition of proof-of-principle data to proceed with full-scale investigations;
• Support the participation of clinical and translational science trainees;
• Show significant promise in securing external funding;
• Provide insights that could be generalizable to other projects or could lead to the adoption of best practices in the prevention and treatment of disease.

Budgeting and Spending Requirements

• Funds can only be used for direct costs.
• Funds cannot be used to support faculty salaries or major equipment purchases.
• Funds cannot be used for inpatient bed charges.
• Funds cannot be used for participant compensation.
• Funds are non-transferable.
• Funds must be used in the 12-month period following IRB approval. Any un-spent funds will be returned to the CTSI at the end of the 12-month funding period.
• Funds must be used for the activities detailed in the application.
• 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.

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 2016 through March 31, 2017, depending on the quality of submissions and budget availability. Awards typically do not exceed $25,000. Larger awards may be considered based on the scientific merit of the project and support contributed to the project from other sources.

Budget Development and Examples

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 must include a written cost estimate for all requested services, including the Clinical Research Center, when applicable, in their proposals. To obtain a cost estimate from the Clinical Research Center, contact Glenna Paguio at paguig@shands.ufl.edu. A time and events table will be required to obtain a cost estimate. A list of CTSI services and the appropriate contacts can be found at: www.ctsi.ufl.edu/research.
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 budget worksheet; and letters of support (if applicable) and cost estimates. 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.