

## CTSI Pilot Awards Fall 2019

### Request for Applications (RFA)

This CTSI RFA will support pilot projects across the full spectrum of clinical and translational research, such as preclinical research; clinical research conducted with human subjects or on material of human origin (e.g., tissues, specimens, cognitive phenomena); epidemiological and behavioral studies; outcomes research and health services research; and the development of new technologies and methodologies.

Three types of 18-month awards are available through this RFA: Trainee, Junior Faculty, and Novel Methods and Technologies.

#### Nature and Purpose of this RFA

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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 the CTSI Pilot Award mechanism will result in one or more publications in a peer-reviewed journal and provide critical preliminary data to support extramural applications.

#### Timelines: Fall 2019

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Pilot Announcement:	<b>Monday, August 26, 2019</b>
Q&A Session #1:	Monday, September 16, 2019 at 2:00 P.M. Location: CTRB 2161 N/S (Gainesville)
Q&A Session #2:	Monday, September 23, 2019 at 12:00 P.M. Location: LRC (Jacksonville)
<b>Application Deadline:</b>	<b>Monday, November 4, 2019 at 5:00 p.m.</b>
Notice of Awards:	Monday, December 16, 2019
Award Funding Period (up to 18 months):	December 16, 2019 – June 16, 2021

## Eligibility

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- Applicants must be a UF faculty member or a UF trainee (residents, graduate students, postdocs and fellows) and meet [UF IRB Investigator qualifications](#).
- Applicants may only submit one application to one CTSI RFA for which they are the principal investigator, but individuals may be listed as a co-investigator on more than one application.
- Recipients of previous CTSI pilot awards are eligible to apply for a Fall 2019 pilot award to support fundamentally new research projects, but only if previous projects have been completed.

## CTSI Pilot Award Criteria

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The CTSI welcomes proposals in response to this RFA for clinical and translational pilot projects. Funding decisions and priority will be based on one or more of the following criteria:

- Utilization of CTSI services. For this RFA, priority will be given to those who include utilization of one or more CTSI services. The CTSI offers facilities and other resources in support of research at UF and we encourage CTSI pilot grant applications to include one or more of these valuable resources.
  - Examples:
    - Biorepository
    - Biostatistics, Epidemiology and Research Design (BERD)
    - Clinical Research Center
    - CTS-IT
    - 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).
- Research activity must be performed at a UF or UF Health facility;
- For clinical research, the application should address the inclusion of special populations, including children, the elderly, the medically underserved and/or underrepresented in the targeted enrollment;
- For clinical research, the application should provide 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.

## Review Process

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- All proposals will be triaged for feasibility and close alignment to the nature and purpose of the RFA, including completeness, feasibility, and budget compliance.
- Applications that meet all criteria will move forward to undergo scientific and statistical review.
- Assigned reviewers will score the proposal utilizing the same criteria used in NIH peer review.
- Final funding decisions are based on reviewer scores and other RFA criteria and principles as listed above.
- Investigators will receive final notice of award or non-award.
- Unapproved applicants from this pilot RFA may not resubmit to a future CTSI pilot RFA within the same cycle (Current cycle: July 1, 2019-June 30, 2020).

## Total Available Funding and Award Amounts

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The CTSI will make \$150,000 available for the Fall 2019 RFA. Awards through this RFA are dependent on the quality of submissions and budget availability. Maximum amounts available for each type of award are as follows:

Type of Award	Amount Available
<i>Trainee</i>	up to \$7,500 per award
<i>Junior Faculty</i>	up to \$20,000 per award
<i>Novel Methods and Technologies</i>	up to \$25,000 per award

## Guidelines by Type of Award

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**Trainees** (resident, graduate student, postdoc or fellow) in a terminal certificate or degree program are eligible to apply for an award of up to \$7,500. This includes individuals seeking an MS, MPH, MD-PhD or PhD (including those enrolled in a T32 program). Trainees must be conducting research under the supervision of a mentor. The qualifications of the mentor are a factor in the review process. Trainees should include a biosketch and letter of support from their mentor(s).

**Junior Faculty** at the Assistant Professor level are eligible to compete for an award of up

to \$20,000. Junior Faculty should include a biosketch and letter of support from their mentor(s).

**Novel Methods and Technologies** awards encourage development of novel methods and technologies relevant to clinical/ translational science. A maximum of \$25,000 will be awarded for each project. Funding will support new methodological (e.g., biostatistics, ethics), technological (e.g., medical device, analytical instrumentation) or treatment developments.

## Budget Development

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For this RFA, priority will be given to those who include utilization of CTSI services. The CTSI offers facilities and other resources in support of research at UF. We encourage pilot grant applications to include one or more of these valuable resources. 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](http://www.ctsi.ufl.edu/research)

See [Application Instructions and Forms](#) for all requirements and details. 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.).

## Budgeting and Spending Guidelines

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- Funds can only be used for direct costs;
- Funds cannot be used to support faculty salaries, student tuition, or other education related expenses;
- Funds cannot be used for the following: major equipment purchases, desktop or laptop computers, mobile devices, software, licensing fees;
- Funds for laboratory testing, assays, biomarkers, and associated supplies may not exceed more than 20% of the total budget;
- Funds cannot be used for inpatient bed charges;
- Funds are not provided for conference registration and related travel expenses;
- Funds are not available for manuscript submissions;
- 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 [CTSI\\_Pilot-Awards-L@lists.ufl.edu](mailto:CTSI_Pilot-Awards-L@lists.ufl.edu).

## Awardee Requirements

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- It is expected that all research supported by CTSI Pilot Project Awards will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural applications.
- Compliance: Awardees must be in compliance with all IRB and/or IACUC policies. Final IRB/IACUC 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/IACUC approval is documented and on file with the CTSI.
- Any pilot projects involving model organisms and/or genomic data must comply with National Institutes of Health policies on sharing model organisms and genomic data.
- Recruitment Reporting: For clinical studies, awardees must submit recruitment and enrollment reports every 3 months after the notice of award. Recruitment and enrollment reports will include enrollment status and inclusion data.
- OnCore Utilization: For clinical studies conducted in Gainesville, utilization of OnCore clinical trials management system is a requirement. Investigators must enter all protocol and project information into OnCore, including enrollment and accrual data.
- General Progress Reporting: For all studies, awardees must submit general progress reports every 6 months after the notice of award. General progress reports will include additional fiscal and scientific status information.
- Serious Adverse Event Reporting: For clinical studies, awardees are 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:
  - 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 [CTSI\\_Pilot-Awards-L@lists.ufl.edu](mailto:CTSI_Pilot-Awards-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

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## [Download the Application Instructions and Forms.](#)

Applications must include the following:

- 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) (if applicable);
- Completed detailed budget for initial budget period;
- CTSI budget justification worksheet;
- Written cost estimates for CTSI services; and
- Letters of support (if applicable).

A preliminary review for completeness of your submission packet may be available if submitted in advance. Proposals that are submitted on the due date of November 4, 2019 that are incomplete and/or otherwise do not follow instructions will be returned to the investigator without review.

## Contact for Information, Questions & Consultations

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Consultation requests with the Pilot RFA team are encouraged. Send requests for consultation and questions to [CTSI\\_Pilot-Awards-L@lists.ufl.edu](mailto:CTSI_Pilot-Awards-L@lists.ufl.edu).

[Information and Q&A Sessions](#) will be offered in both Gainesville and Jacksonville to learn more about this RFA. See Timelines section for specific dates.

Applicants are encouraged to visit [www.ctsi.ufl.edu](http://www.ctsi.ufl.edu) to learn about additional CTSI services available to facilitate research at UF.

In addition, the CTSI Translational Workforce Development Program developed a [Pilot Grantwriters Toolkit](#) as a resource to assist applicants. The toolkit includes a recorded workshop that can be viewed on demand.