UF-FSU CTSA Pilot Awards Spring 2021

Request for Applications (RFA)

Nature and Purpose of this RFA

This RFA is designed to support collaborative projects between Florida State University (FSU) and the University of Florida (UF) that can be accomplished in eighteen months or less and will concentrate on mental health, health disparities, maternal child, and cardiovascular disorders and or/lay critical groundwork for subsequent research while extramural funding opportunities emerge. Applications must include one or more researchers from each institution.

This RFA invites applications across the full spectrum of clinical and translational research, including 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.

It is expected that research supported by this mechanism will result in one or more publications in a peer-reviewed journal and provide critical preliminary data to support extramural applications.

Timelines: Spring 2021

<table>
<thead>
<tr>
<th>Event</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot Announcement</td>
<td>Tuesday, February 2, 2021</td>
</tr>
<tr>
<td>Q&amp;A; RFA &amp; Application Process</td>
<td>Wednesday, February 10, 2021 @ 12pm via Zoom</td>
</tr>
<tr>
<td>Q&amp;A; RFA &amp; Application Process</td>
<td>Wednesday, February 24, 2021 @ 12pm via Zoom</td>
</tr>
<tr>
<td>Letter of Intent (LOI) Deadline</td>
<td>Monday, March 01, 2021 @ 5pm</td>
</tr>
<tr>
<td>(Strongly Encouraged)</td>
<td></td>
</tr>
<tr>
<td>Q&amp;A; Grant Design Studio</td>
<td>Friday, March 12, 2021 @ 3pm via Zoom</td>
</tr>
<tr>
<td>(Invitation Only)</td>
<td></td>
</tr>
<tr>
<td>Application Pre-Review (responsiveness to RFA)</td>
<td>Monday, February 08, 2021 – Monday, March 29, 2021 @ 5pm</td>
</tr>
<tr>
<td>(Optional)</td>
<td></td>
</tr>
<tr>
<td>Application Submission Window</td>
<td>Monday, March 22, 2021 - Monday, April 12, 2021 @ 5pm</td>
</tr>
<tr>
<td>Notice of Awards</td>
<td>Monday, June 28, 2021</td>
</tr>
<tr>
<td>Award Funding Period</td>
<td>Tuesday, July 1, 2021 – Friday, December 30, 2022</td>
</tr>
</tbody>
</table>

The UF-FSU CTSA is supported in part by NIH awards UL1TR001427, KL2TR001429 and TL1TR001428
Eligibility

- Applicants must be a UF or FSU faculty member, early stage investigator, or a trainee (see Application Instructions for more details) and meet UF IRB Investigator qualifications or FSU Investigator Eligibility.

- Applicants may only submit one application to one CTSA 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 Spring 2021 pilot award to support fundamentally new research projects, but only if previous projects have been completed.

- Applicants who submit a letter of intent (LOI) will be invited to attend a Grant Design Studio Q&A with the goal of enhancing the quality of grant preparation and submissions. All applications received will be reviewed regardless of receipt of a LOI or Grant Design Studio Q&A attendance.

CTSI Pilot Award Criteria

The UF-FSU CTSA 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 UF CTSI services. For this RFA, priority will be given to those who include utilization of one or more UF CTSI services. The UF CTSI offers facilities and other resources in support of research at UF-FSU and we encourage pilot grant applications to include one or more of these valuable resources.
  - Examples:
    - Clinical Research Center (CRC)
    - 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 UF CTSI website at [www.ctsi.ufl.edu/research](http://www.ctsi.ufl.edu/research).
  - Consultations with UF CTSI Service leads are highly encouraged for any Investigator intending to utilize a UF CTSI Service in their project.

- Research activity must be performed at a UF/FSU or UF/FSU 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;

**The UF-FSU CTSA** is supported in part by NIH awards UL1TR001427, KL2TR001429 and TL1TR001428
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-FSU 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

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 RFAs within the same cycle (Current cycle: July 1, 2021 - December 30, 2022).

Total Available Funding and Award Amounts

The UF-FSU CTSA will make $100,000 available for the spring 2021 Pilot RFA. Awards through this RFA are dependent on the quality of submissions, collaborations between both universities and budget availability. Awards up to $25,000 each will be available through this RFA.
Budget Development

For this RFA, priority will be given to those who include utilization of UF CTSI services. The UF CTSI offers facilities and other resources in support of research at UF-FSU. We encourage pilot grant applications to include one or more of these valuable resources. In addition, UF CTSI services require cost estimates in writing from UF CTSI Service providers. For a complete list of available resources, please visit the UF CTSI website at 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

- 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 UF-FSU CTSA 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 UF 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.
Awardee Requirements

- It is expected that all research supported by this RFA 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 UF-FSU CTSA.

- 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 and/or the FSU College of Medicine Research Fair 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 this RFA must include a funding citation. The following language should be used: “Research reported in this publication was supported by the UF-FSU CTSA, 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 UF-FSU CTSA 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 UF-FSU CTSA at 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

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 UF CTSI services; and
- Letters of support (if applicable).

Proposals submitted on the due date of Monday, April 12, 2021 that are incomplete and/or otherwise do not follow instructions; will be returned to the investigator without review.

Contact for Information, Questions & Consultations

Consultation requests with the Pilot RFA team are encouraged. Send requests for consultation and questions to CTSI_Pilot-Awards-L@lists.ufl.edu.

Information and Q&A Sessions will be offered via Zoom to learn more about this RFA. See Timelines section for specific dates.

Applicants are encouraged to visit www.ctsi.ufl.edu to learn about additional UF CTSI services available to facilitate research at UF and FSU.

In addition, the UF CTSI Translational Workforce Development Program developed a Pilot Grant Writers Toolkit as a resource to assist applicants. The toolkit includes a recorded workshop that can be viewed on demand.

The UF CTSI is supported in part by NIH awards UL1TR001427, KL2TR001429 and TL1TR001428