UF Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

CTSI PILOT AWARDS Fall 2019

Information Q&A Session

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The UF CTSI is supported in part by NIH Clinical and Translational Science Awards UL1TR001427, KL2TR001429 and TL1TR001428.
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UF CTSI Pilot Program

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.

Recurring Pilot Opportunities:

- **Clinical and Traditional (Current RFA)**
- Translational/Learning Health System

Past Limited/Special Opportunities:

*Metabolomics * STEM-Communications *

*Network Science Interventions
*Pain/Aging/Disability

*UF Informatics Institute and UF Big Data

*Precision Health Initiative *Substance Use-Pain

UF CTSI Pilot Project Awardees 2008-2014

Competitive Awards:

- 125 grants
- $2.2 million
- 856 papers
- 209 protocols approved by the IRB
- 601 external grants with funding of $101.7 million

Award Opportunities

- **This RFA welcomes proposals for Clinical and Traditional pilot projects (formerly patient-oriented and non-patient oriented)**
- **A total of $150,000 is available for this current grant year***

  **Based on quality of proposals and budget availability*
- ***Three types of awards:***

  Trainee - up to $7,500

  Junior Faculty - up to $20,000

  Novel Methods and Technologies - up to $25,000

Timeline

- **Pilot Announcement: Aug 26, 2019**
- **Application Due Date: Mon, Nov 4, 2019 at 5:00 p.m.**
- **Notice of Award: Dec 16, 2019**
- **Award Funding Period: Dec 16, 2019 – June 16, 2021**
- *(18 months)*

Eligibility

UF Faculty

UF Junior Faculty

- Assistant Professor
- Conducted under the supervision of a mentor

UF Trainee

- Resident, Graduate Student, Postdoc, Fellow
- For individuals in a terminal certificate or degree program
- Seeking an MS, MPH, MD-PHD, PHD
- Includes those in a T-32 program
- Conducted under the supervision of a mentor

Eligibility

- Able to meet UF IRB Investigator qualifications
- Only one application as PI
- May be listed as Co-I on more than one proposal
- Past recipients may submit fundamentally new proposals if previous awarded projects have been completed

Award Priorities

- Utilization of CTSI services
- Inclusion of special populations
- Successful plan for recruitment and retention of subjects
- Additional project support and resources
- Multidisciplinary, collaborative and/or inter-institutional
- Emerging technologies and methodologies

Award Priorities

- Rapid acquisition/analysis leading to further investigation
- Supports participation of trainees
- Shows significant promise of external funding
- Generalizable to other projects
- Leads to adoption of best practices in the prevention and treatment of disease

Steps in the Pre-Award Review Process

- **Initial triage of applications for completeness**
- **Only complete proposals are sent for scientific review**
- **At least two scientific reviewers selected for each proposal based on area of expertise, background and COI**
- **Biostatistics review**
- **Scheduled for CTSI Funding Committee review**
- **Award and Non-Award Notices sent on Dec 16, 2019**

Pilot Budgeting and Spending

- Direct Costs only
- Cannot support faculty salaries
- Cannot support student tuition or other education related expenses
- Cannot be used for major equipment purchases
- Funds for laboratory testing, assays, biomarkers, supplies may not exceed 20% of the total budget
- Cannot be used for inpatient bed charges
- Funds are not provided for conference registration and travel

Pilot Budgeting and Spending

- Award funds are non-transferable
- Must be used in the 18 month award period
- No cost extensions are not automatic, contingent on progress
- Unspent funds are returned to CTSI
- Funds must be used according to approved budget activities
- Funds used for CTSI services are provided as non-transferable credit
- Funds contingent on compliance with requirements

ctsi.ufl.edu

It’s all right here →

Research Services Overview

- Pilot Funding
- Research Navigation and Regulatory Assistance
- Study Design & Analysis
- Data, Informatics and IT
- Recruitment Center
- Clinical Research Center
- Core Facilities

Voucher Request

Research Services

The CTSI Service Center provides a range of services and resources to investigators performing translational research across campus.

The CTSI Service Center’s programs, resources and core facilities can assist you in:

DESIGNING A STUDY → | MANAGING DATA AND SOFTWARE → | NAVIGATING REGULATIONS →

RECRUITING PARTICIPANTS → | CONDUCTING RESEARCH → | USING TRANSLATIONAL TECHNOLOGIES →

Not sure where to start? Research navigators can help direct your team to the right resources. Please see the table below for a list of CTSI services and contacts.

Initial consultations for all services are offered at no cost. If a study requires special or extended involvement of staff, cost may be assessed. We will discuss all available options at the first consultation.

CTSI Resources

CTSI Service Providers Available for No-Cost Consultation

Biostatistics
Wei Xue, Research Assistant Professor, qiangxue@phhp.ufl.edu

CTS-Information & Technology
Christopher Barnes, Director CTS-IT, cpb@ufl.edu

REDCap Support (Research Electronic Data Capture)
Taryn Stoffs, REDCap Support Team Lead, tls@ufl.edu

Integrated Data Repository & UF Consent2Share
Alexis Quinones, UF Health Shands, aqui0002@shands.ufl.edu

CTSI Resources

CTSI Service Providers Available for No-Cost Consultation

Clinical Research Center
Janet King, Clinical Research Manager, jking1@ufl.edu

UF Advanced Research Resources
Socorro “Tet” Pata, Research Coordinator, spata@ufl.edu

Recruitment Center
Deaven Hough, Recruitment Specialist, deavenf@ufl.edu

HealthStreet
Beatrice Dorestil, Director of Operations, kerlande24@ufl.edu

CTSI Resources

CTSI Service Providers Available for No-Cost Consultation

Investigational Drug Service (IDS)
Susan Beltz PharmD, IDS@Shands.ufl.edu

CTSI Library Services
Terry Selfe PhD, tselfe1@ufl.edu

MultiSite Studies Support
OneFlorida Clinical Research Consortium
CTSI Trial Innovation Network
SMART IRB

CTSI Resources

CTSI Service Providers Available for No-Cost Consultation

Regulatory Services (IND/IDE)
Sheila Austin, Regulatory Specialist, Sheila.Austin@ufl.edu

Regulatory Services (IRB)
Tiffany Pineda, Research Navigator, tiffany.Danielle@ufl.edu

CTSI Biorepository
Amer Abouhamze, Assistant Director, amer@ufl.edu

Translational Technologies & Core Facilities
Human Imaging, Biobehavioral, Genotyping, Metabolomics, Drug Development

Application Instructions

- Application Instructions and Forms (all on website)

I. Cover sheet (This is a 2 page form)

Number of participants to be enrolled

Total cost of proposed work

Funding from non-CTSI sources

Total funds requested from CTSI * (Attached Budget)

IRB/IACUC status

Signed and dated by PI and Department Chair

Application Instructions

II. Page 2:

- Abstract (200 words or less)
- Translational impact (200 words or less)
- External funding plan (200 words or less)
- Mentoring plan for trainees, junior faculty (200 words or less)

Application Instructions

III. Research Plan (no more than six pages total):

- Project Timeline
- Rationale
- Specific Aims
- Preliminary Studies
- Design and Methodology
- Recruitment Strategy
- Planned Enrollment Table *(Patient-Oriented submissions)*
- References (included within page limit)

Application Instructions

IV. Key Personnel - name, title, UFID and project role

- Biosketches – NIH non-fellowship format ("Do not exceed 5 pages")

V. Budget

- Use the NIH "Detailed Budget for Initial Period" PHS 398 form
- Add our CTSI Budget Justification Worksheet
- Provide written cost estimates for CTSI services (DO NOT FORGET THIS!)

VI. Letters of Support

- Required for Junior faculty and Trainees

Steps in the Post-Award Period

Congratulations! (Now what…)

- Submit IRB/IACUC approval and approved documents
- OnCore utilization (Gainesville patient-oriented projects)
- CRC initiation process (if applicable)
- Subaward requirements addressed (if applicable)
- Chartfield strings established
- Regular monitoring of fund accounts
- Reconciliation, review of project balances
- Progress Reporting – recruitment, general, changes, SAEs
- Close out of award

Awardee Expectations

Publication(s)

- One or more publications in a peer-reviewed journal

Poster/Presentation(s)

- CTSI Research Day
- Scientific Meetings

Extramural Funding

- Provide critical preliminary data to support extramural applications

NIH Requirements

- CTSI Funding Citation *
- NIH Public Access Policy **

Compliance

- IRB/IACUC approval
- OnCore utilization
- NIH policies

Reporting/Notifications

- Progress Reports
- Notification of significant changes
- SAEs

*CTSI Acknowledgement

Please use the following citation language if you receive any CTSI supported services or awards:

"Research reported in this publication was supported by the University of Florida 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."

**NIH Public Access Policy

The NIH Public Access Policy requires scientists to submit final peer-reviewed manuscripts that result from direct costs funded by NIH, and that are accepted for publication on or after April 7, 2008, to the digital archive PubMed Central. Compliance with the NIH Public Access Policy is a legal requirement (Consolidated Appropriations Act of 2008, Pub. L. No. 110-161, Division G, Title II, Section 218).

Information on how to submit manuscripts can be found at: http://publicaccess.nih.gov/submit_process.htm

Recommended Steps for Success

- Consultation(s) – CTSI pilot team
- Consultation(s) – CTSI service providers
- Review Grant Writing Courses, Workshops, Toolkits
- Peer or mentor involvement and review of application
- Visit the CTSI website
- Sign up for the CTSI Quick Links newsletter
- Submit early (courtesy review for RFA requirements)
- Submit by Due Date and on time!

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Application Submissions Contact for Questions: please email

CTSI_Pilot-Awards-L@lists.ufl.edu

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