UF CTSI Learning Health System Initiative
2021-22 Request for Translational Pilot Applications

Timeline

RFA Release Date:	March 5, 2021
Info Session (via Zoom):	March 8 NOON
	March 11, 4 p.m.
Application Deadline:	April 2, 2021
Anticipated Notice of Awards:	May 1, 2021
Anticipated Project Start Date*:	July 1, 2021
Anticipated Funding Period:	July 1, 2021**-June 30, 2022

*IRB approval and NIH prior approval documents are required no later than June 11, 2021.
** IRB and NIH approval must be obtained before the study can begin.

Overview

The UF CTSI Learning Health System Program is pleased to invite applications for Translational Pilot Awards that use a "learning health system" approach to align research and clinical operations to improve health outcomes and advance health equity using informatics, stakeholder engagement, implementation science and other methodologies to address one or more priority areas at UF Health (see below). The Translational Pilot Program is supported in part by the UF-FSU CTSA Award funded through the NIH National Center for Advancing Translational Sciences.

Two twelve-month awards of up to $50,000 each are available for pilot projects that address health-related research questions developed in collaboration with clinicians, patients and community groups or other stakeholders. Research teams should demonstrate an established partnership with clinicians, patients, and other stakeholders as appropriate for the research. Once complete, these pilot projects should provide a solid foundation on which to base applications for extramural funding.

A total of up to $100,000 is available for projects to be funded in the 2021-2022 cycle, depending on the quality of proposals and availability of funds. The Translational Pilot Program is supported in part by the CTSI's Clinical and Translational Science Award funded through the NIH National Center for Advancing Translational Sciences.

Preferred Topics for 2021-2022 Grant Cycle

The CTSI Learning Health System Program is seeking pilot projects focused on health

care topics of interest to UF Health and that have the potential to lead to future extramural funding. Projects can address health care delivery issues such as potentially preventable admissions and readmissions, decision support and/or particular conditions including: hypertension, diabetes, and opioid and other substance use.

Background

The National Academy of Medicine proposed the learning health system as an integrated clinical, operational, and research health system environment focused on improving quality and outcomes of care.[1] The system integrates informatics, implementation science, and other methodologies at the point of care to improve quality and accelerate the translation of scientific discovery into practice. The CTSI Learning Health System Program engages stakeholders and administers the Translational Pilot Program to strengthen learning health system capacity and culture at UF.

Translational Pilot Projects should lead to one or more publications in a peer-reviewed journal and the submission of high-quality, patient-centered applications competitive for funding by NIH, the Agency for Health Care Research and Quality (AHRQ) and/or the Patient-Centered Outcomes Research Institute (PCORI). The CTSI is especially interested in projects to develop and test strategies within UF Health that, if shown to be successful, could be adapted for diverse clinical settings throughout the state to address local needs in collaboration with OneFlorida partners.

All projects must have scientist, clinician and patient engagement along with other stakeholders as relevant to the project, and should contribute data or other innovations that can be used to support further exploration into your team's research questions using one of the following approaches:

- Implementation Science: "Implementation science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice. It seeks to understand the behavior of healthcare professionals and other stakeholders as a key variable in the sustainable uptake, adoption, and implementation of evidence-based interventions. The intent of implementation science and related research is to investigate and address major bottlenecks (e.g. social, behavioral, economic, management) that impede effective implementation, test new approaches to improve health programming, as well as determine a causal relationship between the intervention and its impact." [2]
- Comparative Effectiveness Research (CER): "Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care." Additional information and an expanded definition of CER can be found at the National Library of Medicine website.[3]
- Pragmatic Clinical Trials (PCTs): PCTs are designed to test interventions in the full spectrum of everyday clinical settings in order to maximize applicability and generalizability. More information about PCTs can be found at the NIH Health Care Systems Research Collaboratory's Living Textbook of Pragmatic Clinical Trials, a "collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of PCTs."[4]

Eligibility

- The project PI must be a full-time faculty member at UF or FSU. Applicants are strongly encouraged to include an investigator from each institution and principal investigators must meet the requirements for PI status as specified by their home institution.
- Applicants can only submit one application for which they are the principal investigator, but individuals can be listed as co-investigators on more than one proposal.
- Applicants are strongly encouraged to review the CTSI Pilot Grant Writers' Workshop prior to the development of their pilot proposal.
- Recipients of previous CTSI pilot awards are eligible to apply for awards to support fundamentally new research projects providing that prior awards have been successfully completed.

Application Process and Timeline

- Applications are due April 2 by 5 p.m.
- Applicants will be notified of funding decisions by approximately May 1.
- **Projects selected for funding must be submitted to NIH's National Center for Advancing Translational Sciences (NCATS) for approval before funding can be released and human subject research can begin.** If your project is selected for funding, please be prepared to obtain IRB approval shortly after receiving a funding decision, as IRB approval is part of the documentation required for NCATS review. The project PI/ designee will work with Katie Blackburn to prepare the prior approval documents, which must be submitted to NCATS at least 30 days prior to the research start date.

Review Process and Criteria

All applications will be triaged for completeness, feasibility, likelihood of completing the project in one year, and responsiveness to the RFA. Applications that are accepted will be referred for scientific review. Any applications proposing the use of the OneFlorida Clinical Research Consortium will also require OneFlorida Executive Committee review and approval.

Scientific reviews: Reviewers will use NIH review criteria to score submissions based on scientific merit.

Funding decisions: In addition to scientific review scores, the following criteria will be used in making funding decisions:

- How does the proposed project address the topic categories described in this RFA ***or*** how is the proposed project directly relevant to patient care in a learning healthcare setting?
- How does the project make use of the CTSI infrastructure and/or the OneFlorida Clinical Research Consortium?
- Is the scientific team multidisciplinary? Does it include practicing clinicians as meaningfully-engaged members of the study team? Are patients or other stakeholders meaningfully engaged?
- How does the proposed project address the inclusion of special populations, including children and older adults, in the targeted enrollment, when appropriate?
- How does the proposed project advance the goal of translational science: to bridge the gap between research and practice in the healthcare system?

- Does the proposed project offer a feasible plan for rapidly integrating research findings into clinical practice?
- How will the proposed project contribute generalizable knowledge for the science of translation?
- How do awardees plan to share research findings with clinical parties directly involved in the study?
- Does the proposed project have a high likelihood of receiving further extramural funding?

Budgeting and Spending Requirements

- Funds may not be used to support faculty salaries or for major equipment purchases.
- There will be limits on use of award funds for travel.
- Funds can be used only for direct costs, such as:
    - Graduate student assistance to be hired on an OPS basis.
    - Programming time, statistical support, and data collection activities.
    - Support for study implementation in practice and/or hospital settings.
    - Travel support will only be funded to the extent that it is integral to the completion of the project, attendance at professional meetings will not be funded.
    - Applicants must include a written cost estimate for all requested services, when applicable, in their proposals. A list of CTSI services and the appropriate contacts can be found at: http://www.ctsi.ufl.edu/research.
- Funds must be used for the activities detailed in the application.
- Funds are non-transferable.
- Funds must be used within the project period. Any un-spent funds will be returned to the CTSI at the end of the project period.
- 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.

Awardee Requirements

- Awardees must be in compliance with IRB, UF, FSU, NIH and other applicable policies and regulations. Projects involving human subject research must receive IRB and NIH approval before funds can be released and research activities can begin. NIH approval takes approximately 2 months to receive. **To expedite the approval process, applicants whose proposals will require IRB approval should demonstrate that they have taken steps to prepare submissions so that minimal time will be lost in securing approval**. All UF awardees conducting human subjects research will work with Tiffany Pineda, CTSI Research Navigator, to submit their IRB applications (tiffany.danielle@ufl.edu) and all FSU awardees will work with FSU's Office of Human Subjects (humansubjects@fsu.edu) to submit their IRB applications.

- Funding cannot be released until IRB and NIH approvals are in place.

- Projects that plan to utilize the OneFlorida Clinical Research Consortium are encouraged to schedule a consultation with a member of the OneFlorida Coordinating Center, who can discuss if the consortium is the right fit for your study. Send your request to OneFloridaOperations@health.ufl.edu.

- Awardees must comply with the CTSI Sharing Plan, which includes sections pertaining to sharing model organisms, data, software, and other research resources.

- Awardees must submit progress reports on the fiscal and scientific status, including enrollment status, of the project 3, 6, and 9 months after the notice of award is received. The CTSI Learning Health System Committee will monitor pilot projects and provide support as needed. A final report must be submitted within 6 months of the project's end. Awardees must notify the CTSI @ katherineblackbu@ufl.edu if they anticipate a significant change in the scope of work that would affect the outcome of the project or require re-budgeting or NIH approval. Project teams present their study progress to the LHS Committee twice during the one-year pilot award and to the OneFlorida Executive Committee at the end of the study to engage partners in discussions about adapting promising strategies to their settings.

- Awardees must notify the CTSI at katherineblackbu@ufl.edu if they anticipate a significant change in the scope of work that would affect the outcome of the project or necessitate re-budgeting or NIH approval.

- 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 results in peer-reviewed journals.

- 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. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html. In publications, awardees must cite the CTSA as follows:

  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.

  If the study also uses the OneFlorida Clinical Research Consortium, awardees must cite OneFlorida as follows:

  Research reported in this publication was supported in part by the OneFlorida Clinical Data Network, funded by the Patient-Centered Outcomes Research Institute #CDRN-1501-26692, in part by the OneFlorida Cancer Control Alliance, funded by the Florida Department of Health's James and Esther King Biomedical Research Program #4KB16, and in part 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 Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology, the OneFlorida Clinical Research Consortium, the University of Florida's Clinical and Translational Science Institute, the Florida Department of Health, or the National Institutes of Health.

Full Application Guidelines

Please refer to the cover sheet and application form for complete instructions. Proposals that are incomplete or otherwise do not follow instructions will be returned to the investigator without review.

Keep in mind that proposals will be read by individuals from a range of disciplines. Minimize the use of discipline-specific terminology and provide clear, non-technical explanations.

Proposals should consist of the following sections in this order (follow application instructions for details): cover page; abstract; brief description of translational impact; brief description of how the proposal will lead to external support; mentoring plan for Early Stage Investigators; project proposal/research plan, including a project timeline; NIH biosketches for key personnel, budget, budget justification and cost estimates, and letters of support if applicable.

Applicants will be notified of funding decisions approximately May 1, 2021.

Contact for Questions

Please email questions to Katie Blackburn at katherineblackbu@ufl.edu.

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[1] Committee on the Learning Health Care System in America, Institute of Medicine; Smith M, Saunders R, Stuckhardt L, McGinnis JM, editors. Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. Washington (DC): National Academies Press (US); 2013 May 10. PubMed PMID: 24901184.

[2] National Information Center on Health Services Research and Health Care Technology (NICHSR): https://www.nlm.nih.gov/hsrinfo/implementation_science.html

[3] https://www.nlm.nih.gov/hsrinfo/cer.html: Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations…[Internet.] Federal Coordinating Council for Comparative Effectiveness Research, definition; [cited 28 July 2010].

[4] NIH Health Care Systems Research Collaboratory. Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials. Available at: http://sites.duke.edu/rethinkingclinicaltrials/informed-consent-in-pragmatic-clinical-trials/. Accessed December 23, 2019.