UF Clinical and Translational Science Institute Learning Health System Program: 2020-2021 Request for Translational Pilot Applications

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 "Preferred Topics").

Brief emails of interest are due by 5 p.m. on Friday, January 24, 2020 (see "Application Process and Timeline" for instructions). Twelve-month awards of up to $25,000 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 $75,000 is available for projects to be funded in the 2020-2021 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.

Info Sessions

There will be two information sessions for this RFA. Both sessions will have call-in availability.

- Wednesday, January 8, 2020, 12:30 p.m., Room 2161, UF Clinical and Translational Research Building (Join via Zoom: https://uflphi.zoom.us/j/234668865)
- Thursday, January 9, 2020, 4 p.m., Zoom only: https://uflphi.zoom.us/j/969384259

Preferred Topics for 2020-2021 Grant Cycle

The CTSI Learning Health System Program is currently undertaking a pilot project to understand UF Health patient, clinician, and staff preferences related to Social Determinants of Health, including when and how this information should be collected from patients, and how the information can best be used to connect patients with resources. In preparation to build on this work, the pilot committee encourages applications in response to this RFA with a focus on social determinants of health and linkage to services. Projects with a connection to the rural areas in UF's catchment area are of special interest. Further, projects can address particular conditions and concerns identified across multiple CTSI stakeholder groups including: hypertension, obesity and weight, diabetes, muscle and bone problems, cancer, healthcare delivery and access, mental health, chronic pulmonary disease, digestive disorders, and opioid and other substance use.

Social determinants of health is a key focus area nationally, highlighted in recent National Academy of Medicine publications[1-2] as well as NIH funding strategies and opportunities.[3-4] Potential areas of interest focused on social determinants include:

- Understanding social determinants of health that serve as barriers to patient activation for self-management of chronic conditions

- Novel clinical informatics or other methods to gather and/or report social determinant of health information for utilization by patients and clinicians, such as projects involving MyChart or natural language processing.
- Strategies for integration of geospatial and patient reported social determinants of health
- Use of SDOH information in the development of personalized care models

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.[5] 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." [6]
- 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.[7]
- 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."[8]

Eligibility

- The project PI must be a full-time faculty member at UF (Gainesville or Jacksonville).
- 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.
- 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.

Awardee Requirements

- Awardees must be in compliance with IRB, UF, NIH and other applicable policies and regulations. Awardee projects involving human subject research must receive IRB and NIH approval before funds can be released and human subject research activities can begin. Applicants whose proposals will require IRB approval should demonstrate that they have taken preliminary steps to prepare submissions so that minimal time will be lost in securing approval. Funding cannot be released until appropriate 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 is appended to this RFA.

- CTSI staff will administer award funds. 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 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 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 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.

Application Process and Timeline

- Submit a brief "email of interest" to Katie Blackburn by 5 p.m. on Friday, January 24, 2020 (instructions below). The pilot committee may request a phone meeting for more information from the research team.
- Research teams will be notified by February 7 of approval to submit a full application.
- Teams invited to submit a full proposal will be required to participate in a workshop led by Dr. Tom Pearson on the topic of pilot studies.
- If given approval from the pilot committee, the research team should submit a full application by 5 p.m. on Friday, March 6.
- Applicants will be notified of funding decisions by April 10.
- **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.

Email of Interest

Investigators are required to submit a brief indication of their plans to submit an application by 5 pm on Friday, January 24, 2020. Please submit this email to Katie Blackburn at katherineblackbu@ufl.edu. Emails should include:

- A brief description of your research interest (1-page maximum)
- Information about your stakeholder engagement, including the name(s) of the clinician(s) whom you plan to work with. If you have not identified a specific clinician, please explain your plans to identify and engage a clinician partner.
- Emails will be reviewed for 1) potential to improve health outcomes, 2) availability of interested clinician and patient/community partners, 3) availability of a researcher with appropriate scientific expertise, 4) feasibility of implementing the study, and 5) potential for future funding.

Full Application Guidelines (for planning purposes only)

Note: The following information is provided for planning purposes only. The CTSI will review emails of interest and invite teams to submit full applications by Jan. 31.

Use 0.5-inch margins and Arial 11-point font. 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:

1. *Cover Page*. Include a cover page, that indicates the project title, names of participants, department/college affiliations, and contact information (email and phone numbers for all key participants).

2. *Abstract.* Provide a short paragraph summarizing the proposed project and rationale (<500 words).

3. *Project Description.* The project description should be no longer than 4 pages (an additional 2 pages are allowed for references) and should address the following:

    - Specific Aims
    - Significance
    - Innovation and anticipated impact on practice-based healthcare, hospital care or the translational research process
    - Approach:
        - Engagement Strategies: Include strategies for engagement of key stakeholders (e.g., patients, health system leaders, community clinicians).
        - Study Setting
        - Population, including eligibility criteria for participants
        - Analysis Plan
    - Specific Plans for Future Funding and Dissemination/Implementation if the pilot project is successful (e.g., name specific funding announcements and planned submission dates), as well as plans for reporting of negative results if not successful

4. *Research Team Participants.* Indicate the main participants and their respective roles in the project.

5. *Budget and Justification*. Provide a detailed budget with justification for the funds requested in accordance with the budget and spending parameters outlined below, including an estimate detailing the cost of any requested services from the provider of the service. The budget period is anticipated to begin in 2020 as soon as all necessary approvals are in place (IRB, NCATS, OneFlorida, etc.). Please use NIH form PHS398 for the budget and justification: https://grants.nih.gov/grants/funding/phs398_rev06-2009/phs398.html (page 5).

6. *Project Timeline*. Summarize the timeline for securing approvals and achieving the project's goals. The timeline should be reasonable for the goals set forth. Please use general timeframes (e.g., Month 1).

7. *Appendices*. Include biographical sketches of faculty and if any stakeholders are currently collaborating, include their biosketches. Letters of Support from relevant partners or institutions will also be considered.

Budgeting and Spending Requirements

- Funds may not be used to support faculty salaries.
- There will be limits on use of award funds for travel.
- Funds cannot be used to buy computers or equipment that is not in direct support of the pilot.
- 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.

Full Application Review Process and Criteria

Full applications will be triaged for feasibility and responsiveness to the RFA. Full 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 merit, 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?

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

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[1] National Academies of Sciences, Engineering, and Medicine. 2019. *Integrating Social Care into the Delivery of Health Care: Moving Upstream to Improve the Nation's Health.* Washington, DC: The National Academies Press. https://doi.org/10.17226/25467.

[2] National Academies of Sciences, Engineering, and Medicine. 2016. *A Framework for Educating Health Professionals to Address the Social Determinants of Health*. Washington, DC: The National Academies Press. https://doi.org/10.17226/21923.

[3] Palmer RC, Ismond D, Rodriquez EJ, Kaufman JS. Social Determinants of Health: Future Directions for Health Disparities Research. Am J Public Health. 2019 Jan;109(S1):S70-S71. doi: 10.2105/AJPH.2019.304964. PMID: 30699027; PMCID: PMC6356128. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6356128/

[4] National Institutes of Health Active Funding Opportunities Announcements and Notices "Social Determinants of Health" search results (accessed December 23, 2019): https://grants.nih.gov/funding/SearchGuide/index.html?query=%22social+determinants+of+health%22&x=0&y=0#/

[5] 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.

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

[7] 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].

[8] 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.