CTSI Translational Pilot Program (TPP):

Program Announcement and 2016-17 Request for Applications

Timeline:
Applications are due on Wednesday, May 4, 2016. TPP grantees will have up to 12 months to complete their projects, starting from the date of IRB/NIH approval. A total of up to $250,000 is available for projects to be funded in the 2016-17 cycle. It is estimated that five to eight grants (up to $50,000 each) will be awarded, depending on the quality of proposals and availability of funds.

The Translational Pilot Program Committee will conduct a scientific review on May 16, 2016. Any protocols requiring the use of the OneFlorida Clinical Research Consortium will also require OneFlorida Executive Committee review and approval, which will occur immediately following the scientific review.

The week of May 23rd, applicants will be notified of the decision and provided with instructions about additional documentation that is needed to prepare materials for final approval by NIH. In addition, successful applicants will be asked to prepare their IRB materials. The anticipated start date for the projects is July 8, 2016.

Interested applicants are encouraged to present their ideas for feedback during one of the CTSI’s spring Translational and Implementation Science Studios: February 24, March 23 and April 27. In addition, the Feb. 24 studio (11 a.m. to 1 p.m., CTRB 2161, lunch provided) will include an overview presentation about the Translational Pilot Program and application process. Interested applicants should contact program coordinator Katie Blackburn (katherineblackbu@ufl.edu) at least two weeks in advance of a studio date to reserve a spot.

Purpose, Definitions and Approaches
The University of Florida Clinical and Translational Science Institute (CTSI) was founded in order to speed the translation of scientific discoveries into improved health by strengthening the university’s ability to conduct clinical and translational research. The TPP is supported in part by the CTSI’s Clinical and Translational Science Award (2015-2019) funded through the NIH National Center for Advancing Translational Sciences.

The TPP grant program aims are:

1. To fund pilot or investigational research in areas that are most important to health systems and clinicians based on the needs of their patients;
2. To prepare investigators to successfully seek additional grant funding to work in these important topics; and
3. To contribute to the body of work in translational science and, over time, to advance the quality of translational science at UF.

The NIH National Center for Advancing Translational Sciences defines translation and translational science as follows¹:

- Translation is “the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.”
• Translational science is “the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.”

While study approaches will vary, the TPP is particularly interested in studies using the following approaches:

1) 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.

2) 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 http://www.consort-statement.org/Media/Default/Downloads/Extensions/CONSORT%20Extension%20for%20Pragmatic%20Trials.pdf

3) Implementation Science Studies: “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.”

Focus for 2016 – 2017 Grant Cycle
Preference will be given to research questions that are in one of the three following categories:

1) Institute of Medicine Comparative Effectiveness Research Topics. Of note, the top five research priorities include healthcare delivery systems, racial/ethnic disparities, cardiovascular disease, geriatrics, and functional limitations and disabilities.

2) UF CTSI Stakeholder Priority Topics, which include: hypertension, obesity, diabetes, healthcare access, mental health, and chronic pulmonary disease

3) OneFlorida Health Care Delivery System Clinician and Leader Topics: These topics were identified and prioritized through a series of surveys, focus groups and individual interviews with clinicians and health system leaders in Florida:
   • Create and test predictive algorithms that can be used at the point of care to identify children at high risk for ongoing chronic conditions such as neonatal abstinence syndrome or for subgroups of children (e.g., obese, metabolic syndrome).
   • The effectiveness of multi-level interventions aimed at the health care delivery system and the patient and family on reducing potentially preventable inpatient admissions, readmissions, and emergency department visits.
• Health care delivery system and/or intervention pilot studies focused on individuals with co-occurring physical and mental health conditions to improve their health outcomes and/or quality of care.

Investigators may submit proposals on other topics that are not listed above, including projects that address opportunities to improve the research process. Regardless of the topic, all proposals must provide evidence of stakeholder engagement (e.g., health system leaders and/or clinicians and patients) in the selection of the topic and formulation of the specific aims.

Successful projects will contribute data or other innovations that can be used to support further exploration into the research questions.

Eligibility

• The project PI must be a full-time faculty member at UF

Awardee Requirements

• Awardees must be in compliance with all IRB, UF, NIH and any other applicable policies and regulations. Awardees project 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 used until appropriate approvals are in place.

• 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 Implementation Science Program Operations 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 necessitate re-budgeting or NIH approval.

• 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 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.
Projects utilizing the OneFlorida Clinical Research Consortium have very specific requirements regarding publications and presentations. The OneFlorida Clinical Research Consortium is contractually required to notify PCORI prior to submission of all publications citing the CDRN contract. Awardees must contact onefloridaoperations@health.ufl.edu before preparing publications or presentations.

**Budgeting and Spending Requirements**

- Funds may not be used to support PI salary or equipment.
- There will be limits on use of award funds for travel.
- Funds can be used only for direct costs.
- 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.

**Application Instructions**

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.

1. **Cover Page**. Include a cover page that indicates the participants, department/college affiliations, and contact information.

2. **Abstract**. Provide a short paragraph summary of the proposed project and the rationale.

3. **Project Description**. The project description should be no longer than 4 pages (an additional 2 pages are allowed for references) and should address:
   - 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
     - 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. **Participants**. Indicate the key personnel and their respective roles in the project. Provide NIH biosketches for the key personnel.
5. **Budget and Justification.** Provide a detailed budget with justification for the funds requested. The budget may not exceed $50,000 for 12 months and can include:

- 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](http://www.ctsi.ufl.edu/research).

6. **Timeline.** Summarize the timeline for achieving the project’s goals. The timeline should be reasonable for the study aims. All projects must be completed within 12 months of funding start date.

7. **References.** Do not exceed two pages.

**Review Process and Criteria**

Scientific criteria: All proposals will be reviewed by the Translational Pilot Program Scientific Committee with ad hoc reviewers added as needed for the topic areas.

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

- The proposed project addresses the topic categories described in this RFA or the proposed project is directly relevant to patient care in a learning healthcare setting.
- The use of the CTSI infrastructure and/or the OneFlorida Clinical Research Consortium.
- Is multidisciplinary in terms of the scientific team and includes practicing clinicians and/or patients as a member of the study team.
- The proposed project addresses the inclusion of special populations, including children and the elderly, in the targeted enrollment, when appropriate.
- The proposed project advances the goal of translational science: to bridge the gap between research and practice in the healthcare system.
- The proposed project offers a feasible plan for integrating research findings into clinical practice rapidly.
- The proposed project will contribute generalizable knowledge for the science of translation.
- Awardees agree to share research findings with the clinical parties directly involved in the study.
- The proposed project has 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 Center for Advancing Translational Sciences: [https://ncats.nih.gov/translation/spectrum](https://ncats.nih.gov/translation/spectrum))
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].


Institute of Medicine
http://iom.nationalacademies.org/~media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities/Stand%20Alone%20List%20of%20100%20CER%20Priorities%20for%20web.ashx
UF CTSI Resource Sharing Plan

The University of Florida Clinical and Translational Science Institute (UF CTSI) intends to meet and exceed NIH requirements for sharing of research resources including data and software. The UF CTSI is furthermore committed to incorporating in all its translational workforce development programs competencies that enable workforce members to contribute to resource sharing and reuse, including the development of research consent language that permits broad data reuse.

Model organisms and Genome Wide Association Studies plan. Nothing in the plans of the linked U, K, and T proposals that constitute the UF CTSI submission for a Clinical and Translational Science Award involves model organisms or GWAS directly. However, UF CTSI will implement a policy whereby all pilot projects it funds that involve model organisms and/or GWAS, regardless of funding source, must comply with NIH policies on sharing model organisms and GWAS, as a condition of making the pilot awards. Furthermore, UF CTSI will assist investigators to whom it makes pilot awards with compliance with these policies.

Data sharing plan. The UF CTSI plans to share research, clinical (including EHR), investigator, and program evaluation data as broadly as possible within the limits prescribed by law, regulation, and the principles of ethical human subjects research. Illustrative of this commitment, the UF CTSI and UF Health are already making de-identified clinical data available to the CTSA network for participant recruitment in the NCATS Accrual to Clinical Trials project. Through participation in the OneFlorida Clinical Research Consortium, UF CTSI plans to create multi-directional clinical data sharing among its members for the purposes of research. OneFlorida also requires investigators who use Consortium infrastructure for a study to commit to making de-identified study data available back to the Consortium at the end of the study. This broad data sharing in OneFlorida is accomplished through memoranda of understanding and executed data use agreements. Research using UF Health clinical data other than fully HIPAA de-identified data requires IRB approvals and executed data use agreements, but under these conditions is open to investigators at UF, in OneFlorida, and the CTSI network. UF CTSI and UF Health are committed to sharing clinical data needed for multi-site clinical trials including pragmatic trials and implementation science studies through the Research Electronic Data Importer (RED-I) software, as they have done already with HCV TARGET. OneFlorida also plans to make de-identified, aggregate site-level recruitment and research participation data available to all sites participating in studies using the OneFlorida Consortium infrastructure. UF CTSI is also broadly sharing UF investigator profiles in VIVO format as recommended by the CTSA network in 2011, and will continue to make available data from its Network Science program in this manner. Finally, UF CTSI plans to share its evaluation and tracking data to inform the science of translation.

UF CTSI is also committed to stimulating research data sharing by helping investigators receive academic credit for generating and sharing data sets. To that end, the Center for Advanced Data Capabilities of the UF CTSI biomedical informatics program will offer as a service to investigators the procurement of digital object identifiers or DOIs for their data sets. DOIs enable investigators and those who use their data sets to cite the data sets in publications and other academic writing, thereby generating citation statistics by which to measure the data’s influence on subsequent work. To enable discoverability and promote the visibility of DOI-tagged data sets, the Center will also work with Biomedical and healthCAre Data Discovery and Indexing Ecosystem (BioCADDIE) led by the University of California San Diego to incorporate data sets into the relevant data catalogs in an expeditious manner. As these developments of citable datasets and research data catalogs are emerging, we will also track the evolution of best practices in this regard in the overall NIH Big Data to Knowledge (BD2K) program.

Software sharing plan. All software from this project will be made available freely to researchers and their institutions for educational, research, and non-profit purposes. Furthermore, DOIs are also available to software libraries and BD2K has sought from the research community its input into a software discovery index, through a request for information. UF CTSI has already procured a DOI for the most recent production version of RED-I, specifically doi:10.5281/zenodo.10014. UF CTSI plans to continue the procurement of DOIs for the software artifacts created in this project, and to incorporate them into the anticipated BD2K-sponsored software discovery index.
**Licensing.** All software developed under this project will be freely available for educational, research, and non-profit purposes under the terms of the Berkeley Software Distribution version 3 (BSD-3) software license, which enables all three requirements of the RFA: 1) it makes the software freely available to researchers, healthcare systems, and research institutions and organizations; 2) it permits the dissemination and commercialization of enhanced and/or customized versions of the software and the incorporation of the software or components of it into other software packages; and 3) it includes the ability of individuals outside UF and its collaborating institutions to modify the source code and to share modifications with other colleagues. Under BSD-3, no claims of suitability, and no warranty of any kind, are made. Under BSD-3, software can be modified, but under no conditions can anyone assert ownership over the code or its modifications, including commercial entities. UF CTSI reserves the right to use successive versions of BSD beyond BSD-3 that come into being during the project, but only under the stipulation that it continues to meet all the criteria set forth here.

**Availability.** UF CTSI commits to making the software developed in this project freely available under the terms of the BSD-3 license to all biomedical researchers, educators and institutions in the non-profit sector such as education, research institutions and government laboratories. Software will be available for free, unrestricted download under the terms of the BSD-3 license from UF and/or an open-source repository like SourceForge and GitHub. For example, the REDCap Electronic Data Integrator (RED-I) software discussed in the Research Plan is freely downloadable under BSD-3 from the GitHub site at: [https://github.com/ctsit/redi/](https://github.com/ctsit/redi/).

**Open source community.** In addition to making source code for the software publicly available, the CTSI biomedical informatics program will cultivate an active open-source development community by providing extensive developer documentation and plug-in architectures enabling others to contribute new functionality to the software.

**Enhancements.** UF CTSI anticipates that a community of practice will develop around each major software application released during this work, and that this community will support the software application after the proposal period. Community activity includes the submission of enhancements for inclusion in future releases. The R Project for Statistical Computing and VIVO project are examples of vibrant open source communities supporting complex software systems for research and translation. The communities fostered will operate in a similar fashion, establishing an archive and providing mirror sites for downloads, as well as on-line technical support through a blog and wiki. The VIVO community, now hosted by the Duraspace organization, speaks to UF CTSI’s ability to create self-sustaining open-source communities.

**Required software components.** Software developed by UF CTSI strives to reuse other open source components and not require any commercial software to run or host the software. Specifically, VIVO requires the use of the open-source Apache Tomcat, the Jena semantic web open-source library, and the open-source Virtuoso triple store. Shibboleth is required for support of federated identity use cases. VIVO, RED-I and their required components can be run on a wide variety of operating systems, both open source and commercial, and on a wide-range of commercially available hardware. It is strongly recommended that all UF CTSI created software be deployed in accord with all institutional information security and privacy requirements.

**Other research resources sharing plan.** UF CTSI also plans to share other research resources with the CTSA network and beyond, including policies, practices, education and training materials, model consent forms, and templates for memoranda of understanding and legal agreements and contracts. Illustrative of this commitment, UF CTSI has already presented the university’s “Bridge Partnership” to the CTSA network as a model for efficient contracting processes. Per the research plan of this proposal, UF CTSI is also committed to extending its Bridge model to multi-site trials in the CTSA network.

In addition to free and open-source software, UF CTSI is also committed to free and open access to data standards including biomedical ontologies. Just as researchers are free to use SI units of measure and the chemical symbols of the elements without restriction or need to purchase a license, they ought to be free to standardize scientific data using ontologies in a free and open manner. Furthermore, the BD2K program has a strong interest in creating and fostering scientific communities that create and support such open standards. These communities enable the standards to change at the pace which science changes, and to be consistent with the latest scientific knowledge. UF CTSI therefore commits to releasing under the Creative Commons CC-BY license all ontological artifacts whose creation and ongoing development and maintenance is under its control, including the demographics ontology, the drug ontology, and the ontology of medically related social entities. The CC-BY license allows free use of the ontology without restriction, including commercial use, with proper attribution of the source of the ontology. Furthermore, personnel in the biomedical informatics program of UF CTSI are active participants in the communities supporting other ontologies released as free and open.
resources, including the ontology for general medical science, the ontology of biomedical investigations, the biobanking ontology, and more.