

UF CTSI Precision Health Initiative Spring 2020 Request for Pilot Applications

Timeline

RFA Release Date: Friday, April 17, 2020

Info Session (remote participation available): April 28, 2020, 10:00-11:00 a.m.

Zoom: https://uflphi.zoom.us/j/975656326

Application Deadline: Friday, May 15, 2020 by 5 p.m.

Anticipated Notice of Awards: June 15, 2020 Anticipated Submission for NIH Approval: July 15, 2020

Anticipated Funding Period: 12 months from date of NIH approval

Purpose and Areas of Focus

The University of Florida Clinical and Translational Science Institute (UF CTSI) Precision Health Initiative is pleased to invite applications for pilot projects that help fulfill the CTSI Precision Health Initiative's mission of developing methods, interventions, or integrative models with the potential to advance precision medicine and precision public health. Pilot project grants are one-year competitive awards, up to \$50,000, to provide funding for early stage projects.

Available funding categories are defined below.

- Precision medicine: An "approach for disease prevention and treatment that takes into account individual differences in lifestyle, environment, and biology."
- Precision public health: "Improving the ability to prevent disease, promote health, and reduce health disparities in populations by: 1) applying emerging methods and technologies for measuring disease, pathogens, exposures, behaviors, and susceptibility in populations; 2) developing policies and targeted implementation programs to improve health."²

Precision Health Pilot Projects may involve any combination of multisource data, including but not limited to molecular (e.g., genomics, metabolomics, proteomics); imaging (e.g., MRI, pathology slides, or dermatology images); patient-generated (e.g., mobile health devices or apps); clinical (e.g., electronic health records or devices, insurance claims); public health surveillance; social determinants of health; economic; or environmental.

Eligibility

 This call is open to investigators at UF and Florida State University (FSU). Applicants are strongly encouraged to include an investigator from each institution, and principal

¹ NIH All of Us Program: https://allofus.nih.gov/about/about-all-us-research-program

² Precision Public Health and Precision Medicine: Two Peas in a Pod (https://blogs.cdc.gov/genomics/2015/03/02/precision-public/)

investigators (PIs) must meet the requirements for PI status as specified by their home institution.

- Applicants must assemble project teams that include investigators from at least two
 colleges, and must include at least one trainee (i.e., graduate student, postdoc, resident) or
 junior faculty member for a mentored research experience. Single-investigator proposals
 are not eligible.
- Applicants can only submit one application for which they are the PI, 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, as long as previous projects have been completed.
- Animal studies are not allowed.

Review Process and Criteria

All proposals will be triaged for completeness, feasibility to complete the project in one year, and responsiveness to the RFA. Proposals that are accepted will be referred for scientific review.

Scientific review: A scientific review of all accepted applications will be conducted. Reviewers will use NIH review criteria to score submissions based on scientific merit.

Funding decisions: Funding priority for this year's program will be given to meritorious proposals utilizing OneFlorida data. In addition to scientific review scores, the CTSI will consider the following criteria in making funding decisions, specifically whether proposals:

- Utilize CTSI resources (see "Related Services and Resources" on page 4);
- Are multidisciplinary, collaborative, and/or inter-institutional in the clinical and translational research enterprise;
- Encourage the development or use of emerging methodologies and technologies that may affect future research;
- Allow rapid acquisition and/or analysis of proof-of-concept data to proceed with full-scale investigations;
- Support the participation of clinical and translational science trainees;
- Show significant promise in securing external funding;
- Provide insights that could be generalizable to other projects or could lead to the adoption of best practices in precision health.

Budgeting and Spending Requirements

- Funds can only be used for direct costs.
- Funds cannot be used to support faculty salaries or major equipment purchases.
- Funds are non-transferable.
- Funds must be used in the 12-month period following their release (funds will not be released until NIH prior approval is received). Any unspent funds must be returned to the CTSI at the end of the 12-month funding period.
- Funds must be used for the activities detailed in the application.

Funds requested for CTSI services will be provided as non-transferable credit. A list of CTSI services and contacts can be found at www.ctsi.ufl.edu/research.

Awardee Requirements

- Awardees must comply with their respective IRBs, NIH, and other applicable policies and regulations. Projects involving human subjects research <u>must</u> receive IRB and <u>NIH approval</u> before funds can be released and research can begin. NIH approval takes approximately two months to receive. To expedite the approval process, 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. All UF awardees conducting human subjects research will work with Tiffany Pineda, CTSI Research Navigator, to submit their IRB applications (<u>tiffany.danielle@ufl.edu</u>) and all FSU awardees will work with FSU's Office of Human Subjects (<u>humansubjects@fsu.edu</u>) to submit their IRB applications.
- Funding cannot be released until NIH and IRB approvals are in place.
- Project teams 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 advise if the consortium is the right fit for the study. Send requests to OneFloridaOperations@health.ufl.edu.
- Awardees must comply with the <u>CTSI Resource Sharing Plan</u>, which includes sections pertaining to sharing model organisms, data, software, and other research resources.
- Awardees must submit a 6-month and a final progress report. In addition, each December awardees will be required to update a one-page project report and – if conducting NIHdefined clinical research – inclusion enrollment monitoring data for submission as part of the CTSI's annual progress report to the NIH. Continued funding during the award period is contingent on compliance with requirements and adequate progress in meeting the project timeline.
- Awardees are expected to present their research during the annual UF CTSI Research Day and/or UF Precision Medicine Conference in the form of a poster or oral presentation, the CTSI Precision Health Forum, and at scientific meetings. Contribution of relevant data to the CTSI Precision Health Initiative data commons (in development) is also expected.
- It is likely that CTSI Pilot Projects may result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural applications.
 Therefore, following project completion, awardees will be asked to report subsequent publications and funding awards resulting from their pilot projects. In accordance with NIH requirements:
 - All presentations and publications resulting from work funded by a CTSI Pilot Award must include a funding citation. The following language should be used: "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 UL1 TR001427. 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 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.
 - 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, its Board of Governors, or Methodology Committee, 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."
- Awardees must notify the CTSI at <u>elizabetheddy@ufl.edu</u> if they anticipate a significant change in the scope of work that would affect the outcome of the project or necessitate rebudgeting or NIH approval.

Application Instructions and Timeline

- Applications must include a cover sheet signed by the PI and her/his department chair; abstract; brief description of translational impact; brief description of how the proposal will lead to external support; mentoring plan for trainees and junior faculty; project proposal/research plan, including a project timeline; NIH biosketches for key personnel; budget, budget justification, and cost estimates; and letters of support. Download the cover sheet and application form for complete instructions. Proposals that are incomplete or do not follow instructions will be returned without review.
- Applicants will be notified of funding decisions by June 15, 2020.
- 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 subjects 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 Elizabeth Eddy to prepare the prior approval documents, which must be submitted to NCATS at least 30 days prior to the research start date.

Related Services and Resources

The following resources may be of interest for potential projects:

- UF CTSI services and resources:
 - o Pilot Grantwriters' Toolkit
 - UF Health Precision Medicine Program
 - UF HSC Libraries Guide: Precision Public Health
 - Biostatistics, Epidemiology and Research Design Program
 - Biomedical Informatics Program
 - Southeast Center for Integrated Metabolomics open-source tools
 - UF Health Integrated Data Repository
 - OneFlorida Data Trust

- o For additional CTSI research services, visit: https://www.ctsi.ufl.edu/research/
- <u>UF Informatics Institute</u> fellows programs, student organization and other resources
- <u>UFIT Research Computing</u> resources: <u>HiPerGator</u>, <u>ResShield and ResVault</u>

Contact for Questions

Please email Elizabeth Eddy, MPH at <u>elizabetheddy@ufl.edu</u> or Terra Bradley, PhD at <u>terra.bradley@med.fsu.edu</u> with any questions about this RFA or the application process.