

University of Rochester Clinical and Translational Science Institute Digital Health Seedling Award Program- Request for Applications

Application Deadline: February 8, 2021
Projects Beginning July 1, 2021

The purpose of the Digital Health Seedling Award Program by the University of Rochester Clinical and Translational Science Institute (UR CTSI) is to promote innovative, high-risk proposals that advance the development, approval, adoption and use of innovative digital health tools, methods and approaches. This includes fostering new cross campus, multidisciplinary collaborations to advance a digital health research network across the University of Rochester. Digital health opportunities and gaps were explored during the University of Rochester Digital Health Data Retreat on October 30, 2020. Preference will be given to proposals that are innovative, interdisciplinary and have a high potential for significant impact.

One seedling will be awarded for \$25,000 in total funding (depending on availability of funding), beginning on July 1, 2021 and ending on June 30, 2022. The award also includes access to data science support from the Rochester Data Science Consortium, with a range of expertise in health data analysis to potentially support digital health applications.

Program Details

Eligibility: The principal investigators (PI) on all proposals must be a full-time faculty member at the University of Rochester. Each faculty member can participate in only one application in any capacity.

Eligible Research: Applications may exploit a range of digital health approaches, tools and data, including topics in the areas of: electronic medical records, sensors and mobile technologies, Real World Data/Evidence, social media, and other approaches and tools focused on advancing clinical research and addressing regulatory science needs.

Review Criteria: The seedling review process coordinated by the program officers will consider the following criteria:

- 1) **Innovation:** Innovative, high-risk/high-reward proposals that advance digital health and inform regulatory science needs will be prioritized.
- 2) **Strategic Impact:** Projects should move into areas that are expected to grow in significance. Proposals that develop or utilize emerging digital health technologies, real world data/evidence and digital biomarkers, focused on UR areas of strength (e.g., data science, AI/ML, sensors, neurosciences, cardiology, cancer, imaging and optics) will be favorably considered. This includes aligning with the opportunities and gaps noted in the UR Digital Health Retreat.
- 3) **Multidisciplinary:** Multidisciplinary projects that also clearly leverage cross-campus collaborations are strongly encouraged.

Important Application Dates:

- **February 8, 2021 at 5:00 PM – Proposals must be received** via [electronic submission](#).
- **March 8, 2021** – Notification of award will be made.
- **July 1, 2021** – Anticipated start date of award.
- **June 30, 2022** – Award period ends. No carry-forward of any funds will be allowed.

Submitting a Proposal

Electronic Submission

[Proposals must be submitted electronically.](#) For questions regarding the submission process, please contact Karen Grabowski at: Karen_Grabowski@URMC.Rochester.edu

Application

Format: The following information must be provided:

- (1) Application Cover Page: (limited to 1 page), which includes:
 - a) Title of the project
 - b) Applicant PI's name, contact information and ORCID ID
 - c) Co-investigators names, contact information and ORCID IDs
 - d) Name and contact information for the department administrator or grants administrator
 - e) Amount of money requested*
 - f) Potential data science support/expertise that could benefit the project (Please contact the program officer/Scott Steele to discuss plans in advance)
 - g) Involvement of human subjects or vertebrate animals and status of approvals

* *Funds may not go to support faculty salaries*
- (2) Specific Aims: (limited to 1 page, font size no smaller than Arial 11 point) which includes the following:
 - a) Project title and PI name
 - b) A description of how the proposal is responsive to the Program RFA
 - c) Overall goals of the Project
 - d) A brief description of each of the specific aims
- (3) Research Plan: (limited to 3 pages, font size no smaller than Arial 11 point) which includes the following:
 - a) Significance
 - b) Innovation (and any technology/tools development)
 - c) Approach
 - d) Brief timeline with milestones
 - e) Outline of plans for follow-on funding/next steps
 - f) References (not included in page limit but attached in this file)
- (4) Biosketches: NIH or NSF Bios for all participating Faculty Members (all assembled into one file)
- (5) Current Support: Does the proposed project build upon/extend current externally funded research? If so, provide a brief bulleted list of source(s) of support. Additionally, attest that the proposed project is not funded through another mechanism.
- (6) Budget: Use [NIH Budget Form PHS398 Form Page 4](#), with brief narrative Budget Justification
- (7) Regulatory Information: (no page limit, font size no smaller than Arial 11 point) which includes the following:
 - a) Human Subjects Approvals, if applicable
 - b) Vertebrate Animals Approvals, if applicable
 - c) Any plans to utilize Select Agents, if applicable
 - d) Multi-PI Plan, if applicable

Proof of IACUC, IRB, RSRB and/or UCAR review and approval is not required at the time of submission, but will be required before a final award is made.

Notes:

- a) *Include the page number and name of the contact PI in the footer of all pages of the proposal.*
- b) *No letters of support are permitted.*

Requirements if funds are awarded

1. **IRB and UCAR Approvals:** All necessary IRB and UCAR approvals will be required before a final award is made.
2. **Delayed Onset Human Subjects Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any seedling funded research involving human subjects. Accordingly, the IRB-approved protocol and other materials must be submitted to the NIH at least 30 days prior to the project start date. UR CTSI personnel will work with awardees to meet these requirements.
3. **Prior Approval of Vertebrate Animals Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any seedling funded research involving vertebrate animals. UCAR approval documentation and other materials must be submitted to the NIH at least 30 days prior to the project start date. UR CTSI personnel will work with awardees to meet these requirements.
4. **Publications:** All publications that benefit in whole or in part from support provided by the UR CTSI must:
 - a. Comply with the [NIH Public Access Policy](#): Assistance with the compliance process is available through the Miner Library.
 - b. Acknowledge UR CTSI grant funding. We recommend use of the following language: “The project described in this publication was supported by the University of Rochester CTSA award number UL1 TR002001 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
5. **ORCID IDs:** All key personnel on the project must obtain an ORCID ID which provides a persistent digital identifier that the investigator owns and controls, and that distinguishes the investigator from every other researcher.
6. **Clinical Trials:**
 - a. To satisfy the expectations of NCATS, the funder of the CTSA program, award recipients conducting an NIH-defined Clinical Trial must also complete [Good Clinical Practice \(GCP\)](#) training. The PI must certify that this training has been completed when the delayed onset human subjects research materials are submitted to NCATS for review. Please review the [NIH definition of a clinical trial](#).
 - b. All applicable clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see the [UR CTSI Regulatory Support webpages](#).

Contacts

For additional information, please contact one of the following.

For questions on submitting the application:

Karen Grabowski
Karen_Grabowski@URMC.Rochester.edu

For scientific or programmatic questions on the seedling program:

Scott Steele, PhD
scott.steele@rochester.edu

Jean-Philippe Couderc, PhD
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