Digital Health Seedling Award Program
University of Rochester
Clinical and Translational Science Institute

Request for Applications

Application Deadline: March 27, 2023
Projects Beginning July 1, 2023

The purpose of the Digital Health Seedling Award Program (DHSAP) 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 program is part of the CTSI Digital Health and Regulatory Science Core and includes fostering new cross campus, multidisciplinary collaborations to advance a digital health research network across the University of Rochester. Preference will be given to proposals that are innovative, interdisciplinary and have a high potential for significant impact.

One seedling will be awarded for up to $25,000 in total funding *(depending on availability of funding)*

Starting date is July 1st, 2023 and ending on June 30th, 2024

The award also includes access to data science consultations from the UR Health Lab and 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 or MPI) must be full-time faculty members at the University of Rochester. Each faculty member can participate in only one application as the PI. Co-investigators may be from institutions other than the University of Rochester.

Eligible Research: Applications may utilize a range of digital health methods, 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 focused on advancing clinical research and addressing regulatory science needs. This includes priorities outlined in the 2022 FDA Focus Areas of Regulatory Science (see Unleashing the Power of Data), the FDA Digital Health Center of Excellence and digital health approaches to advance the development of Drug Development Tools and Medical Device Development Tools.

Eligible Clinical Trials: The NIH institute funding the UR CTSI (the National Center for Advancing Translational Sciences, or NCATS), can only provide direct support for clinical trials ranging from Phase 1 through Phase 2A; therefore Phase 2B clinical trials or those of subsequent phases are not eligible for the UR CTSI pilot project program. NCATS defines Phase 2 clinical trials as those that are designed to test

drugs for efficacy and side effects in a limited number of patients. Phase 2A trials provide data for exposure-response in patients, while Phase 2B trials provide data for dose-ranging in patients.

Review Criteria: The review process of the DHSAP is coordinated by the program officers and will include a review committee that 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 measures (including biomarkers and patient reported outcomes), 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 opportunities and gaps to advance digital health research at the University of Rochester.
3) **Multidisciplinary**: Multidisciplinary projects that also clearly leverage cross-campus collaborations are strongly encouraged.

Following the review process, funding recommendations are made to the UR CTSI Executive Team for final approval.

Important Application Dates:

Proposal submission deadline (electronic submission only)	March 27, 2023
Notification of award	May 1, 2023
Start date of award	July 1, 2023
Award period ends. No carry-forward of any funds will be allowed.	June 30, 2024

Allowable Costs

The program will support costs normally allowable for NIH-funded research projects, except that funding cannot be used to support faculty salary. Trainee salary support is permitted, but must be justified in the proposal. Facilities and administrative costs or “indirects” are required for subcontracts with other institutions and will be paid from the direct costs of the award.

Resubmissions

Only one resubmission of a previously submitted proposal is allowed. New proposals need to be changed substantively to address prior review concerns.

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 in the REDCap submission form:

(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/digital health consultation that could benefit the project (Please contact the program officer/Jean-Phillipe Couderc 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) NIH PHS 398 Form Page 1 Face Page (items 1-7 only). Please note that, if awarded, the proposal title will be posted on the CTSI website.

(3) 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

(4) 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)

(5) Biosketches: NIH or NSF Biosketches for all participating Faculty Members (all assembled into one file)

(6) 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. (Attestation Template)

(7) Budget: Use NIH Budget Form PHS 398 Form Page 4, with a brief narrative Budget Justification

a) On Form Page 4, include effort for all positions, whether funding is requested or not.
b) Clearly indicate which personnel are investigators and which are other significant contributors, as defined in the UR CTSI cost-sharing information sheet.
c) No carryforward is permitted; therefore all funds must be spent during the funding period. Accordingly, if publication costs are included in the budget, these costs must be paid during the funding period.
d) If budgeting for technology items (computers, iPads, etc.), please note that they need to be used 100% for this project during the project period and must be properly justified in the budget

justification. If the equipment will not be used 100% for this project, please budget for the proportion of total costs of equipment that is represented by this project's use of proposed equipment.

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

(9) CTSI Sign-off Form: Please upload the completed CTSI Signoff Form. Please note the CTSI signoff form is CTSI specific and is not submitted to ORPA.

10) Subcontract: If funds will be going to an institution other than the University of Rochester (UR), indirect costs are required and must be paid from the award. Mary Lyons must be contacted at mary_lyons@urmc.rochester.edu prior to submission of the proposal to discuss the requirements of the subcontract, including a letter of intent. The items below must be uploaded into the submission system as a single PDF. Please note that Form Page 4 (Detailed Budget for one-year project period) for the subcontract and the budget justification for the subcontract must also be included in the main PDF of the proposal, following Form Page 4 and the budget justification for the University of Rochester portion of the budget.

a. Scope of Work to be performed by the subaward. Creation of this document should be a joint effort between the UR PI and the subaward PI.
b. NIH PHS 398 Form Page 1: Face Page. This must be completely filled out, including the signature of the institutional signing official.
c. Budget for the subaward on NIH PHS 398 Form Page 4: Detailed Budget for Initial Budget Period
d. Budget justification for the subaward
e. Checklist page showing whether indirect costs are requested. If indirect costs are requested, they will be taken from the direct costs of the award.
f. Attachment 3B: Research Subaward Agreement: Subrecipient Contacts

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

1. **IRB and UCAR Approvals:** All necessary IRB and UCAR approvals will be required prior to expenditure of funds.
2. **Single IRB for Multi-Site Projects Using the Same Protocol**: If the same protocol will be used to conduct your research at multiple sites, NIH requires the use of a single IRB. Office for Human Subject Protection staff will provide guidance in this process. Please note that there may be regulatory costs associated with use of a single IRB that would need to be included in the budget.
3. **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 such as a recruitment and retention plan; protection of human subjects; inclusion of women, minorities, and children; and planned enrollment 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. **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.
5. **2 CRF 200 Procurement Principles Training**: All University of Rochester Principal Investigators on the project and each person that will initiate purchases must provide documentation that they have completed the 2 CFR 200 Procurement Principles training available in MyPath.
6. **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."
7. **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.
8. **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 questions regarding application submission:

Karen Grabowski Karen_Grabowski@URMC.Rochester.edu

For scientific or programmatic questions regarding the seedling program:

Jean-Philippe Couderc, PhD, MBA Jean-Philippe.Couderc@heart.rochester.edu

Joan Adamo, PhD Joan_Adamo@urmc.rochester.edu