

Processes and Methods Pilot Grant Program Step 1 Application Instructions Funding Period: 10/01/19 – 1/31/2020

Submissions accepted: August 20th, 2019-September 16th, 2019
Application submission deadline: September 16th, 2019

For questions regarding these instructions, please visit <https://cctst.uc.edu/programs/pilot/processes> or contact Krista Newland at Krista.Newland@uc.edu.

1. **Background:** The Center for Clinical and Translational Science and Training (CCTST) is supported by the NIH Clinical and Translational Science Award (CTSA) and institutional support from University of Cincinnati (UC) and Cincinnati Children's Hospital Medical Center (CCHMC). The mission of the CCTST is to stimulate research that has the potential to positively impact human health. The Processes and Methods pilot grant mechanism is designed to enable investigators at all levels to explore ways to improve the efficiency and effectiveness of the processes and methods used in clinical and translational research.
2. **Purpose of grants:** The purpose of this announcement is to solicit brief, 1-page proposals for processes and methods projects that can ultimately lead to larger research grants. This two-step pilot grant program is designed to support clinical research professionals as well as patient advocacy groups at a local, regional, or national level. Examples of previous awards have included funding for research designed to improve complex data acquisition and harmonization methods as well as innovative methods for improving recruitment of underrepresented minorities and vulnerable populations. The Processes and Methods grants awarded in this step will provide seed funds for developing a long-term (2 to 5 year) research proposal focused on advancing specific processes and/or methods deemed important to clinical and translational research. Investigators awarded in step one of this grant program will be invited to step two, and will then have four months to produce a more complete 6-page research proposal that includes background, specific aims, significance and innovation, and approach sections, along with an estimated budget not to exceed \$40,000/year in direct costs. Priority thematic areas include:
 - 1) **Methods for facilitating the transfer of Electronic Medical Record data to research databases.**
 - 2) **Methods for improving the application of artificial intelligence and/or deep learning methods needed for decision making in clinical research.**
 - 3) **Methods for improved risk-based monitoring algorithms for auditing and validating clinical research data.**
 - 4) **Methods for detecting and improving upon barriers to implementing adaptive study designs in clinical research, including but not limited to statistical equating methods, operational and logistic details, and regulatory considerations.**
 - 5) **Improved methods in the use of passive, as well as active sensors for obtaining clinical and epidemiologic data.**
 - 6) **Previously submitted proposals to the CCTST Processes and Methods Grants Program that received external reviews but were not funded may be re-submitted: use the one-page proposal format to outline how the revised full proposal will respond to the reviewer comments received in the previous cycle.**
3. **Eligibility:** Applications will be accepted from faculty or staff from all University of Cincinnati campuses, the Academic Health Center (CCHMC, UC, VA Medical Center,), or any of the regional colleges including Xavier University, Mount Saint Joseph University, Northern Kentucky University, Thomas More College, and Miami University. This program is open to members of the Greater Cincinnati community and patient advocacy groups at a local, regional or national level. Advanced degrees (MD, PhD, MD-PhD or equivalent) are not required for eligibility. Collaborative groups of investigators spanning multiple disciplines and programs are strongly encouraged. Submissions from underrepresented and

minority investigators are also encouraged. Investigators who have have received CCTST funding in the past 12 months are not eligible for Processes and Methods funding.

4. **CCTST Membership:** All applicants for Processes and Methods pilot grant consideration must be CCTST members. CCTST membership is free and open to all. For more information about CCTST membership and our online membership registration form go to <http://cctst.uc.edu/user/register>.
5. **Process:** Step 1 Applicants must submit a 1-page preliminary proposal in the format listed below by **September 16th, 2019**. Funding requests of up to \$5,000 are acceptable for this step. Funds for the initial \$5,000 award may not be used to support faculty salaries or salaries of the investigators but can be used for support staff or other expenses related to the application. Awards made in Step 1 of this funding mechanism must be fully **utilized by January 31st, 2020**. THERE WILL BE NO CARRYOVER OF AWARDS BEYOND January 31st, 2020.

Investigators awarded in step 1 of this grant program will have four months to produce a 6-page full proposal and apply for step 2. The step 2 application should include background and scientific merit of your research, specific aims, significance and how your research will facilitate clinical and translational research more broadly, innovation, and approach sections, along with a budget not to exceed \$40,000/year of direct costs for a 12 month period that must be contained within the 6-page limit. The more complete 6-page proposal budget may include limited offset of faculty/investigator salaries (up to 15% effort). A separate RFA will be provided with further instructions to investigators who successfully complete step 1 and are invited to apply for step 2.

6. **Application submission:** Applications must be submitted through the **CCTST Competition and Awards Program Site (CCAPS):** <https://ccaps.research.cchmc.org/welcome>. Log in using your UC ("6+2") or CCHMC username and password. If you do not have a UC or CCHMC username and password, please contact Krista Newland at Krista.Newland@uc.edu or 513 803-5593 to obtain one.
7. **Signatures:** The signatures of all participating investigators and their respective division director, departmental chairperson(s), or organization leader are required.
8. **Application forms and guidelines:** Applications must be assembled as a single PDF file and submitted through CCAPS before midnight of the application submission deadline date. The application form was modified from the PHS 398 form located at <http://Grants.Nih.Gov/Grants/Funding/Phs398/Phs398.html> and is attached. This RFA announcement is also published on the CCTST website under Funding Opportunities, <http://cctst.uc.edu/funding> or under Processes and Methods Pilot Grant Program, <http://cctst.uc.edu/programs/pilot/processes>.
9. **Composition of research proposal:** Proposals for Step 1 should include a face page, budget (which should not be included as a separate page, but as a section in your 1-page proposal), NIH biosketch (if not available, a resume or CV can be submitted) and a 1-page brief description of the project (excluding references) including the following items:
 - a) Cite any prior CCTST funding, resulting grant submissions and outcomes.
 - b) Background and scientific merit of the research.
 - c) Hypothesis or aims.
 - d) A clear, itemized, one or two sentence description of how the funds will be spent (maximum of \$5,000).
 - e) How this award might position you to apply for additional extramural support in a related area.
 - f) Attestations that:
 - 1) The current Processes and Methods proposal does not overlap with other CCTST funding for key personnel.
 - 2) You will notify CCTST of future grant applications (submitted, funding received, denied) and comply with CCTST queries and requests for information.
 - 3) Any publications deriving from this research will acknowledge the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program, grant 5UL1TR001425-02.

Please note that additional support will be given to awardees for access to data management and biostatistical support through Research Central as needed and available . Care should be taken to include brief but relevant details on expected outcomes, potential algorithms, training needs, and programming software languages as well as the specific areas of science that can be improved with the proposed processes/methods. The research proposal must be submitted to the **CCTST Competition and Awards Program Site (CCAPS):**<https://ccaps.research.cchmc.org/welcome> by **September 16th, 2019.**

- 10. Review criteria and process:** Applications will be evaluated based on the strengths and weaknesses of the proposal, fidelity with the RFA, scientific innovation, and potential impact of the work on improving the processes/methods within our scientific community. Proposals will be reviewed by members of the CCTST executive committee as well as a panel of external peer reviewers.
- 11. Progress report:** Annually you will be asked about any new additions to the progress of this project, including any patents, publications or grants that were enabled by this grant support.