

PART 1. OVERVIEW INFORMATION

Funding Opportunity Title	<i>CTSI Community-initiated Translational Research Pilot Program</i>
Awarding Organization	Utah Clinical and Translational Science Institute (CTSI)
Federal Prime Sponsor	National Institutes of Health (NIH) / National Center for Advancing Translational Sciences (NCATS)
Summary of the Funding Opportunity Purpose	Community-initiated translational research pilot projects that focus on community-identified health-related needs and involve collaborations between community organizations and researchers. It is expected that the research supported by each of these pilot awards will result in one or more publications and/or presentations, and will collect data that will be used to apply for funding from NIH or other funders to expand and continue the projects.
Eligibility Criteria	A collaboration between the following: <ul style="list-style-type: none"> a. leader(s) of a community organization located in Utah b. researcher(s) affiliated with a Utah CTSI organization – University of Utah, Utah Department of Health, Veterans Affairs Salt Lake City Health Care System, or Intermountain Healthcare.
Award Budget	Up to \$60,000 Requested budgets should be based on the proposed project needs. No proposal may exceed a request of \$60,000. Awards will be given based on merit and funding availability. Funds must be used within the granting period – no extensions will be granted.

Key Dates

Posted Date	June 25, 2021
Joint Letter of Intent Due Date	August 31, 2021 at 5:00 p.m. Submit by email to Breanne.johnson@hsc.utah.edu (see Section II for further details)
Application Due Date	November 10, 2021 at 5:00 pm REDCap Application link will be provided upon submission of the Letter of Intent (see end of guidelines for further details)
Merit Review	November 11 – December 13, 2021
Award Notification	December 20, 2021
Earliest Start Date	March 1, 2022 (pending NIH/NCATS prior approval)
Award Project Period	March 1, 2022 through February 28, 2023

TABLE OF CONTENTS

- Part 1. Overview Information
- Part 2. Full Text of the Announcement
 - Section I. Funding Opportunity Description
 - Section II. Joint Letter of Intent Requirements
 - Section II. Project Requirements
 - Section III. Budget Guidelines
 - Section IV. IRB Guidelines
 - Section V. Application Information
 - Section VI. Program Contact
 - Section VII. Community Health Needs Assessment Resources

PART 2. FULL TEXT OF THE ANNOUNCEMENT

Section I. Funding Opportunity Description

The Community-initiated Translational Research Pilot Program focuses on community-identified health-related needs and involves collaborations between community organizations and CTSI-affiliated researchers (see eligibility requirements above for affiliated institutions). Please visit <https://ctsi.utah.edu/> for updates and releases on funding opportunities.

Goals of the Pilot Program

- To support development of research collaborations between community organizations/leaders and researchers.
- To fund pilot projects which collect data that will be used to apply for larger federal grants or other funding, with the expectation that the leader(s) of the community organization will be Multi-PIs, co-investigators, or key personnel on these proposals.
 - Assistance is available through the CTSI to both identify funding opportunities and to assist in the application process. Please contact Breanne Johnson, 801-525-2385 or breanne.johnson@hsc.utah.edu for additional information.

Translational Research

“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.” (<https://ncats.nih.gov/files/translation-factsheet.pdf>)

Broadly, there are five types of translational research that span the “bench to bedside” and “bedside-to-community” continuum. Four types of translational research will be funded through this opportunity

- **T1** research translates the discoveries made by basic science research (T0) to initial studies in humans. These studies identify new methods of diagnosing illness, new treatments, or new methods of preventing illness and improving health*. For new drugs, these studies determine if the drug can safely be used in humans and the safe dose. This stage includes Phase 1 clinical trials and other pilot studies.
- **T2** research translates the results from T1 studies to larger groups of people, carefully studying how well or under what conditions a particular treatment (for example, drug or medical device) or approach (for example, behavior change program) works. Researchers use data from these studies to design and test improvements. This stage includes Phase 2 and Phase 3 clinical trials, and can include randomized control trials, carefully matched comparison studies and other methods for testing the effectiveness of a new approach.
- **T3** research translates findings from T2 studies to broader groups of people, including communities and health care practices. This research evaluates the supports and barriers to wide-spread adoption of the new approach. This stage includes Phase 4 clinical trials and outcomes research.
- **T4** research translates the findings from T3 studies to studying health outcomes of entire communities and populations. Studies seek to determine the effectiveness of efforts to prevent, diagnose and treat

diseases as well as the multiple factors that impact health (such as social determinants of health). The findings provide guidance for improving programs or developing new ones.

*By “health” we mean the Seven Domains of Health – physical, social, emotional, intellectual, environmental, financial, and spiritual. For the Pilot Program, projects can also address developing the biomedical workforce from early ages through career preparation.

Identification of Community Health Needs

The proposed project must address a documented health-related need(s) identified by a community organization. The community organization may have previously conducted a needs assessment or the need(s) may have been identified in data collected by another entity (see Community Health Needs Assessment Resources at the end of this document). Given the number of needs assessments that are available, the Pilot Program will not fund additional needs assessments unless a strong case can be made for why this is needed. However, the Pilot Program will fund research on community-identified ways to best address a particular health need.

Section II. Project Requirements

Joint Letter of Intent

Investigators are **required** to submit a Joint Letter of Intent by **August 31, 2021** in order to submit a full application to this funding opportunity. The letter of intent should include the following information:

- Project Title
- Brief Summary of Proposed Research
- Community Organization Involved
 - Name of the leader who will serve as co-Principal Investigator
 - Email address
 - Telephone
- CTSI-Affiliated Researcher Involved
 - Researcher’s position and affiliation
 - Email address
 - Telephone
- Include signatures of both the community leader and the CTSI-affiliated researcher

Please email the completed Letter of Intent directly to Breanne Johnson at breanne.johnson@hsc.utah.edu. If you have any questions or concerns regarding submission of the letter of intent, please contact Breanne Johnson at 801-525-2385 or breanne.johnson@hsc.utah.edu.

Requirements

Proposed projects are encouraged to utilize CTSI resources. Many resources are available including statistical support; engagement sessions/focus groups/interviews/workshops with community members, patients and/or other stakeholders; and more. These resources can be viewed at <https://ctsi.utah.edu/>

- The community leader and researcher are strongly encouraged to meet with each CTSI resource that will be utilized to discuss the proposed project and the resources available to support it.
- Letters of support should be obtained from these CTSI resources, detailing the support that will be provided. These letters should be addressed to both the community leader and the researcher.

All proposals selected for funding will require completion and proof of Research Ethics and Good Clinical Practice training.

- For researchers and institutional key personnel this is satisfied by a CITI certificate of completion
- Community leaders will be provided training and certification by University of Utah Institutional Review Board personnel, which will be arranged by the CTSI Community Collaboration and Engagement Team

For funded projects, the co-investigators will participate in a 1-year mentored fellowship with the CTSI Community Collaboration and Engagement Team (CCET). They and their project team members will participate in a project kick-off meeting and regular follow-up meetings, designed to support equitable collaboration by all team members. Our goal is to support all project partners in building their capacity for community-based participatory research.

Co-investigators selected to receive funding will be expected to submit to the CTSI the following reports, co-signed by both investigators:

- Progress Report at six months after the project begins.
- Final Progress Report at the end of the funded project; this report must be received within 30 days of the end of the project.
- Progress Update Report one year after the end of the project, detailing any additional progress on the project, any submitted publications about the project, and all grant applications (pending or funded) relating to the pilot project.

Co-investigators selected to receive funding also are expected to:

- Submit one or more grant proposals to NIH or other funding agency, to expand or more broadly implement the project.
 - Assistance is available through the CTSI to both identify funding opportunities and to assist in the application process. Please contact the program contacts listed on this announcement for further information.
- Publish their research findings in scholarly, peer-reviewed journals, if data of appropriate quality is collected and make presentations about their project at professional conferences.
 - Peer-reviewed journal articles must be submitted to PubMed Central, the NIH digital archive of biomedical and life sciences journal literature. See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>
- Share the project and research findings with the community(s) that were involved in the research through presentations and/or other means with broad reach.

All publications, grants, and presentations resulting from CTSI-funded research must cite the CTSI as a contributing source of support. Details for how to do this can be found at:

<https://ctsi.utah.edu/administration/citing>

Section III. Budget Guidelines

Due to the collaborative nature of this proposal, budget guidelines are listed for the community partner and the affiliated researcher separately as regulations apply differently. There is not a set funding amount that must go to each category, however please ensure funds are budgeted and spent in accordance with the below regulations. It is recommended that you discuss potential budget expenses with the Program Contact on this announcement prior to submission.

Community Partner Budget Guidelines

Typical expenses may include:

- Incentives for research participants
- Payments or other incentives for Community Health Workers or other individuals to recruit participants, carry out a program and/or collect data
- Payment for Community Leaders for work performed outside of normal job scope when necessary for the completion of the project
- Supplies needed to conduct the research project
- Charges for CTSI services such as engagement sessions, survey design, or statistical analysis

The following costs are **not** covered by these awards:

- Alcoholic Beverages

Affiliated Researcher Budget Guidelines

Typical expenses include:

- Incentives for research participants
- Technical supplies needed to conduct the research project
- Charges for CTSI services such as engagement sessions, survey design, or statistical analysis

The following costs are **not** covered by these awards:

- Faculty salaries
- Post-doctoral salaries for those already listed as a trainee on a T grant
- Graduate student stipends or tuition
- Meals or hospitality (i.e., no food, beverages, or alcohol)
- Travel that is not directly related to the conduct of research (including travel to present findings)
- Other items typically supported by indirect costs
- Monetary incentives for health care clinics to participate in research

Awards are not transferable to any other organization.

Section IV. IRB Guidelines

All applications must include proof of IRB Submission or proof that the research is not classified as “human subjects” research.

- Applications that are classified as “human subjects” research that do not include proof of IRB submission will be administratively disqualified.
 - Proof of IRB approval for “human subjects” projects must be submitted to the CTSI during the Just in Time period in order to receive funding. The Just in Time period is expected to occur between December 2021 – February 2022.
- **The title of the IRB-approved protocol must match the title of the proposed pilot project.**

Section V. Application Information

General Instructions

Concise communication of the relevant information will help to demonstrate effective proposal writing and communication skills, and the likelihood of success in developing the full, competitive proposals to follow these pilots.

The Utah Community-initiated Translational Research Pilot Program **requires** all applicants to adhere to the following instructions when preparing their application. **Failure to** adhere to instructions may result in administrative rejection of the application. For assistance or any questions, please see the administrative contact listed at the end of this announcement.

1. **University of Utah Internal Process:** The Pilot Program Application **does not** go through the University of Utah Office of Sponsored Projects (OSP). A University of Utah eProposal should not be created for this application. Do not send this application to OSP.
2. **Font Size:** 11 point, not condensed
3. **Font Type:** Arial
4. **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm)
5. **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
6. **Margins:** At least 0.5 inch (1.27 cm) in all directions

7. Internet URLs: Other than the NIH Biographical Sketches or Bibliography & References Cited documents, URLs directing reviewers to websites that contain additional information about the proposed research are unallowable. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage.
8. Proposal Organization: The content of the proposal should be structured as outlined in the Program Application instructions below.
9. Tables, Graphs, Figures, etc.: All tables, graphs, figures, diagrams, and charts must be included within the overall page limit.
10. Recommended Document Size: Size of each document cannot exceed 15 MB.

Program Application

Applications should include, in the following order:

1. Cover Letter signed by each participating investigator (researcher and community leader)
2. Research Plan, in the following order:
 - a. Specific Aims
 - b. Background and Significance
 - c. Innovation
 - d. Research Design and Methods
3. Bibliography and Literature Cited
4. Plan to Obtain Additional Funding
5. Detailed Budget (*template provided at REDCap link*)
6. Budget Justification
7. NIH Biographical Sketches for key personnel
8. Proof of IRB Submission or proof of non-human subjects research
9. Letters of Support: if applicable
10. No appendices are allowed

For assistance with the application requirements please contact Breanne Johnson at 801-525-2385 or breanne.johnson@hsc.utah.edu. This may include any questions pertaining to the application, preparation of documentation, resources, and other aid.

1. Cover Letter

Include a brief letter addressed to the CTSI with the following information:

- Name of the funding opportunity announcement to which the grant proposal is being submitted
- Project title
- A brief description of the ways in which the co-investigators have worked together to jointly develop the grant proposal
- A brief description of the roles and responsibilities each co-investigator will have if the project is funded
- Signature, title, and affiliation of each co-investigator

2. Research Plan (*maximum of 5 pages*)

Organize the Research Plan in the order specified below, using the guidelines provided.

- Start each section with the appropriate section heading: Specific Aims, Background and Significance, Innovation, and Research Design and Methods.
- Provide the full reference for each journal article or other source in the Bibliography and Literature Cited section (which is not included in the page limits).

A. Specific Aims

In this section, state concisely the goals of the proposed research. Focus your specific aims to ones that can be reasonably achieved, given the 12-month timeframe and available funding.

List the specific proposed research objectives, e.g., to answer specific research questions, test a stated hypothesis, create a novel program, begin testing whether a particular program or approach

will lead to positive health outcomes in a particular community or population, solve or begin solving a specific problem, or address a critical barrier to progress in the field. *When writing Specific Aims, consider the following:*

- What is your overall goal?
- What do you propose to do in this project?
- What outcomes do you aim to achieve?

B. Background and Significance

A sound research project should demonstrate the context of the proposed work within the team's prior work and/or the work of others.

- Identify the community-identified need(s) the project will address and the needs assessment on which identification of this need is based.
- Explain the importance of the community-identified need that the proposed project addresses, both to the community and to science.
- Describe the scientific basis for the proposed project, including analysis of the strengths and weaknesses of current approaches (if any) to addressing the community-identified need, and published research or preliminary data that support your plan for addressing this need.
- Explain how the proposed project will improve the health of community members, advance scientific knowledge, and/or improve clinical practice, if the proposed aims are achieved.

C. Innovation

- Describe what is new and innovative about your proposed project.
- In what ways will your approach be different from current programs or practices?
- Why do you think (hypothesize) that your approach/program will be more effective than current approaches/programs?

D. Research Design and Methods

- Describe any prior research/work (Preliminary Studies) by your team that have provided information or data relevant to your proposed project. (*preliminary data are not required*)
- Describe your plan for achieving the specific aims of the project.
- Describe the research design and methods you will use and how they will result in robust and unbiased results.
- Describe how the research data will be collected, analyzed, and interpreted.
- Describe any potential problems in carrying out your research plan and how you plan to address them if they arise.
- Briefly describe how results or findings from the research will be disseminated to the community.
- Briefly describe any manuscripts you expect to come out of your proposed project and the journal(s) to which you plan to submit them.
- Include a Timeline that lists each major task for the proposed research, who will be responsible for carrying it out, and the months when you anticipate carrying it out.

3. Bibliography & References Cited (*no page limit; not included in 5-page limit for Research Plan*)

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the **names of all authors** (in the same sequence in which they appear in the publication), the article and journal or book title, volume number, page numbers, and year of publication. Provide any references cited in this application utilizing the [American Medical Association Style JAMA](#).

4. Plan to Obtain Additional Funding (*maximum of 1 page*)

- Identify the specific funding opportunity(s) to which you plan to apply, using the pilot data obtained from the proposed project.
- Describe the ways in which the pilot project data will support and strengthen these grant proposals.
- Include a timeline for grant submission, including the target date for submitting your application.

5. Detailed Budget for Community Organization and Affiliated Researcher (*template available at REDCap link*)

Include an itemized table for the budget, listing categories and costs separately for the community organization involved and the affiliated researcher in accordance with the budget guidelines listed in this FOA. For example:

- Salaries and/or Wages
 - List each named person on a separate line
 - List each type of person who is not specifically named, on a separate line
 - Show salary/wage and benefits for each person or type of person
- Materials and Supplies
- Research Participant Support
- Consultants (such as for CTSI services)
- Travel
- Registration fee(s) and/or travel to present the research at professional conferences/meetings

6. Budget Justification (*no page limit*)

Provide a detailed justification for each expense listed in the budget.

Any travel for community leaders to present at professional conferences/meetings must name the conference/meeting, list who will attend, and provide a detailed budget for the conference.

7. NIH Biographical Sketches (*5-page limit for each person*)

- Each Co-Investigator must submit a NIH Biographical Sketch.
- The current NIH biographical sketch template form and samples can be found at: <https://grants.nih.gov/grants/forms/biosketch.htm>
- The CTSI Grants and Contracts Officer, Breanne Johnson is available to assist in preparing NIH Biosketches.

8. Human Subjects

- Proof of IRB Submission (or proof of non-human subjects research) (*if applicable, no page limit*)
 - i. ***Proof of Institutional Review Board (IRB) Approval or Submission***
Documentation of IRB Approval or proof of IRB application submission must be provided for all research involving human participants. The CTSI will **administratively withdraw** applications that do not include either proof of IRB submission or approval.

9. Letters of Support (*if applicable, no page limit*)

Include letters of support and/or collaboration from individuals or organizations whose cooperation/collaboration is important for conducting the proposed research project.

Section VI. Program Contact

Breanne Johnson: Utah CTSI Grants and Contracts Officer:
Building 379, 2-220.24
27 S. Mario Capecchi Dr.,
Salt Lake City, Utah 84113
Phone: 801-525-2385; Email: breanne.johnson@hsc.utah.edu

The CTSI is available to assist in the preparation of this proposal, including determining extramural funding opportunities and mechanisms, finding an affiliated researcher, and answering any questions. Community leaders and researchers may reach out to the CTSI at any point during the granting period, or after, for assistance in grant submission to funding mechanisms. For more information, please contact Breanne Johnson at the above listed information.

Section VII. Community Health Needs Assessment Resources

Examples of existing needs assessments are listed below. Resources for specific communities can be located via an internet search using “community health needs assessment” and the location of interest.

Healthy Salt Lake

- 2017 Salt Lake County Community Health Assessment - http://www.healthysaltlake.org/content/sites/saltlake/Documents/Community_Health_Assessment.pdf
- Community Health Needs Assessment Guide to conducting a community health needs assessment and developing an implementation strategy - <http://www.healthysaltlake.org/index.php?module=CHNA&controller=index&action=index>

Intermountain Healthcare

- Community Health Needs Assessment and Implementation Strategy (reports for 23 hospitals in Utah and southeast Idaho) - <https://intermountainhealthcare.org/about/who-we-are/chna-reports/>

University of Utah

- University of Utah Health, Community Health Needs Assessment Implementation Plan, 2018-2020 - <https://healthcare.utah.edu/about/pdfs/chna-uuh-2018-2020.pdf>
- University Neuropsychiatric Institute, Community Health Needs Assessment, Implementation Plan & Completion Report 2018-2020 <https://healthcare.utah.edu/about/pdfs/chna-uni-public-report-2018-2020.pdf>

Utah Department of Health

- Office of Health Disparities - <https://health.utah.gov/disparities/index.html>
- Utah State Health Assessment 2019 - <https://ibis.health.utah.gov/ibisph-view/pdf/opha/publication/SHARReport2019.pdf>

Section IX. Just in Time Period

Applications will be selected for funding within the University of Utah CTSI. Upon receiving notice of intent to fund from the University of Utah, the application will be submitted to the NIH for final funding approval. The CTSI Prior Approval Navigator, Ginger Bair, will coordinate with selected applicants throughout this process.

Section VIII. REDCap Submission

REDCap Submission Basic Information

- The REDCap submission link will be provided to those who submit a Letter of Intent.
- For assistance with REDCap, please feel free to contact the program contacts listed on this announcement.

Application Checklist

Application	Submission Method	Length/Limit
<input type="checkbox"/> Applicant and Project Information		
<ul style="list-style-type: none"> • Applicant & Contact Information 	Enter into REDCap	Not Applicable
<ul style="list-style-type: none"> • Other Project Information 	Enter into REDCap	Not Applicable
<input type="checkbox"/> Pilot Application	Save file as “CI Pilot Application_PI Last Name.pdf” and upload as a <u>single file</u>	
<ul style="list-style-type: none"> • Cover Letter 		No page limit
<ul style="list-style-type: none"> • Research Plan <ul style="list-style-type: none"> • Specific aims • Background/Significance/Preliminary Studies • Innovation • Research design and methods • Bibliography and Literature Cited <i>(Please note: References can be placed at the end of the Research Plan and will not be counted towards the page limits)</i> 		5-page limit
<ul style="list-style-type: none"> • Specific plan to obtain additional funding 		1-page limit
<ul style="list-style-type: none"> • Detailed Budget Justification 		No page limit
<ul style="list-style-type: none"> • Community Co-Investigator NIH Biosketch 		5-page limit
<ul style="list-style-type: none"> • Researcher Co-Investigator NIH Biosketch 		5-page limit
<ul style="list-style-type: none"> • Other Key Personnel NIH Biosketches 		5-page limit each
<ul style="list-style-type: none"> • Letters of Support 		No page limit
<ul style="list-style-type: none"> • Human Subjects Related Documentation <i>(If applicable)</i> <ul style="list-style-type: none"> • Proof of IRB Approval or Submission 		No page limit
<input type="checkbox"/> Detailed Budget Template	Save as “DetailedBudget_PI Last Name.pdf” and upload	Not Applicable