2025 Clinical and Translational Science (CTS) Research Program
Request For Applications
July 1, 2026 - June 30, 2029

Overview

The Clinical and Translational Science Collaborative (CTSC) CTS Research Program seeks applications for 2–3-year Pilot Projects. **The specific goal of the CTS Research Program is to support projects promoting overall health and reducing the burden of chronic illness through innovative technology**. We are interested in proposals aligned with the collaborative's overall goals, including understanding health challenges and overcoming barriers to recruitment into clinical research, integration of collaborators throughout the research process, and implementation of novel research programs in clinical and community settings. Proposals should address truly significant challenges in CTS research that would be scalable across populations if successful. Proposals will provide generalizable CTS innovations or operational strategies that can be applied to other translational research projects to make the research process more efficient, effective, and impactful.

Technology must be applied innovatively or to a novel population/problem, but the technology itself need not be new. Innovative technology examples include using technology to improve health outcomes, ensuring access to new biomedical science and technology, and using tools to promote self-monitoring of chronic illnesses. In addition, tools like artificial intelligence-powered conversational agents, electronic systems to identify research participants, and technology-based tools to assess and/or monitor risk factors and outcomes to support the care of patients at home.

The goals of the CTS Research Program are:

- Multi-methodological research projects that make high-impact and meaningful differences in addressing and combating healthcare challenges
- Innovative and unique combination of established research methods into powerful studies that focus on the significant burden of conditions disproportionately affecting rural and other populations.
- Accelerate the translation of established research methods into novel modalities that bring solutions to more patients within a population or a wider service geography.
- Develop new approaches and collaborations that can contribute to the generalizability and scalability of clinical and translational science and initiatives for all populations.

Priority Areas

Although applications are welcome in the broad domains of clinical and translational research, we are especially interested in applications covering the following priority areas:

- Projects addressing clinical translational science that is, disease-agnostic projects that focus on the process of turning research results into real-world applications to improve health
- Innovative, multi-center (CTSC partner sites) clinical studies that integrate community and clinical partners to ensure health
  improvements for all
- Dissemination & Implementation of research evidence and innovation in clinical practice
- Projects that leverage Cosmos or TriNetX
- Health issues related to the significant burden of conditions that disproportionately affect rural and other populations.
- Innovative Implementation Science methods that promote the uptake of research findings into routine healthcare in clinical or policy contexts
- Interventions at community and/or clinical practices to promote overall health

- Studies on methods to improve the clinical and translational research process

Both Translational Research and Translational Science projects are eligible (See Appendix 1).

Eligibility and Review Criteria

1. The PI must be a CWRU, full-time faculty member (or the equivalent) from CWRU, the Cleveland Clinic, MetroHealth, University Hospitals, or Louis Stokes Cleveland VA Medical Center, and eligible to be a PI for an NIH grant. Multiple PI applications are highly encouraged. CoIs may include community health leaders and/or researchers at NEOMED and/or the University of Toledo.
2. All applications must include 2 or more CTSC partner institutions, or they will not be considered for funding.
3. All CWRU Schools may apply for this initiative.
4. Applications from new investigators are highly encouraged.
5. The research will address a mid- to late-stage clinical research (T2/T3/T4; see Appendix 1) of community health with an articulated, quantitative, and/or qualitative outcome result leading to a change in health using Translational Research or Translational Science approaches.

In addition, the CTS Program will review applications for the following aspects:

- How well is your project aligned with the overall goals of the CTSC?
- What is innovative about using technology to care for patients with chronic illness? (e.g., innovative technology, application to a novel patient population or condition, or novel approach to technology that complements standard of care).
- How will you engage all under-studied populations in conducting research and implementing the study results?
- What is the general approach for implementation and anticipated outcomes of your project?
- How will relevant partners be engaged in the project? (e.g., community groups, providers, patient-partners)?
- What are the composition and qualifications of the team members who will lead the project?
- How will the results of the project be disseminated?
- What are future plans for sustaining or advancing the project through additional research?

Budget Considerations (See Appendix 2)

CWRU will serve as the fiscal entity through which CTSC funds will be distributed and administered. The pilot award amount will depend on the scope and type of the project. Awards may involve the incorporation of novel methodologies, technology, or programming for translational studies and using CTSC resources. The budget must be well justified. Awardees are encouraged to supplement awards with additional institutional, departmental, or private funds. Funds may be allocated between $125,000-$175,000 per year, depending on the project's duration. A specific budget justification should be detailed. Although the project can span up to 3 years, investigators should include the details justifying why several years are required for the project's success and clear budgetary plans delineated by year.

Trans-Disciplinary and Trans-Institutional Team Science

Includes co-investigators with diverse skills from different schools, colleges, or community organizations is encouraged. A project where one of the investigators provides access (to data, specimens, or patients) is less acceptable than one where knowledge or skill sets enhance the CTS Research Program pilot and lead to building a Team to continue the theme.

Change of Institutions/Transfers

Recipients may not transfer these awards to another institution or another individual. Reallocations in the approved budget require prior written approval before expenditure. Awardees must give 90 days notice of any change in Institution, and funds will be prorated when an applicant leaves the Institution.

Letter of Intent (LOI) Submission Process

Investigators interested in submitting applications to the CTS Research Program can first schedule a consultation with the CTSC Pilot Program faculty lead and Research Navigator before submitting a Letter of Intent (LOI) in InfoReady. To schedule a consultation, select "Research Navigation Services" in SPARCRequest.

Investigators submitting a proposal appropriate to the goals of the CTS Research Program will be invited to submit a complete application (See Appendix 3).

See the following guidance. Information must be entered/uploaded into InfoReady. The LOI is a brief summary of the proposal (**one-page maximum**) that must address the following:

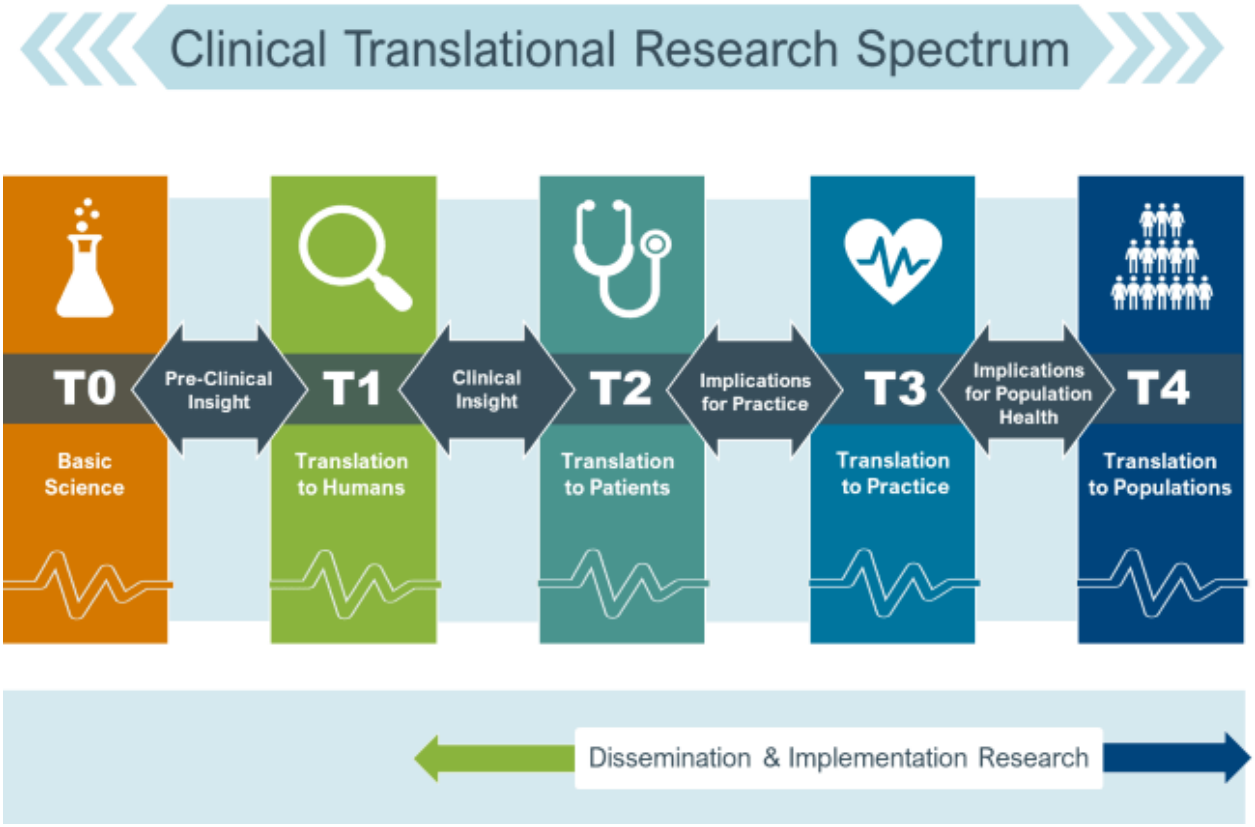
- Project Title
- Names and Affiliations of PI, Co-PIs, Co-Investigators and Collaborators; ensure all Project Site(s) are included
- A brief, focused project summary.
    - **Question/Hypothesis of the study** - This section should be about ¼ of a page and describe the overall health-related goal addressed by the hypothesis/premise/scientific question. The Pilot can be within a larger development plan but should stand alone as a milestone to the larger effort.
    - **Innovation/Translation** - This section should be about ¼ of a page; describe how your project fills a critical translational gap and discuss anticipated results.
    - **Feasibility** - This section should be about ¼ of a page and describe the feasible elements of your one-year study; include potential roadblocks or concerns in this section.
    - **Project Milestones** - This should describe the project plan in about ¼ page. For this project's scope, we suggest no more than 3 temporal or decision-making milestones that can be achieved with the budget allowed and in the time frame selected. Please include an estimate of how long each milestone will take, why it is critical to the proposal, and any long-term plans.
    - **Budget Summary** - statement of how the award funds would be utilized and distributed
    - **Human Subjects** - If the study requires IRB approval, include a statement outlining plans to obtain IRB approval by March 31, 2026, dates of submission and/or approval.
    - **Intellectual Property** - Has this project been submitted to or received Intellectual Property protection? If yes, do you plan to file an invention disclosure? If not, would you like help to learn more?
    - **Special Considerations** - Statement whether this project is planned to have any foreign components, MOUs, or sub-awards.

Important Dates

TBD	CTS Research Program Technical Webinar

June 30, 2025, 11:59 PM	LOI submission due via InfoReady
August 1, 2025	LOI results announced. Successful applicants will be invited to submit a full proposal that will include more details on the premise, goals, milestones, personnel, and detailed budget, along with the IRB submission status (revision or approval).
October 1, 2025	Full Application Deadline
(Mid-December) December 15, 2025	CTS Research Program Awards announced
March 31, 2026	Any applications with IRBs must have IRB approval IN PLACE
July 1, 2026	CTS Research Program projects start date
June 30, 2029	CTS Research Program: all projects must end

Appendix 1: Translational Spectrum and Definitions



Translation	The process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.
Translational Research	The endeavor to traverse a particular step of the translational process for a particular target or disease.
Translational Science	The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Translational Science is disease agnostic.

Basic Science (T0)*

The basic research stage of translation is research to understand the human condition and environment by studying the biological, social, and behavioral mechanisms that underlie health and disease. Methods include preclinical or animal studies and association studies using large datasets.

Preclinical Research (T1)*
The preclinical research stage of translation is the first stage of translation research, which is the process of moving research findings from the lab to patients and communities. This involves preclinical studies, developing protocols for human clinical trials, and finding new diagnosis, treatment, and prevention methods.
*Basic Science (T0) and Preclinical Research (T1) are NOT the focus of the CTS Research Program Pilot Award. (Instead, we invite you to apply for a CTSC Voucher or Core Utilization Pilot for these types of projects)

The areas of funding for this RFA include:

Clinical Research (T2)
The clinical research stage of translation transfers findings from clinical studies or clinical trials to practice settings and communities, where the findings improve health. This stage includes translation to patients, including Phase 2 and 3 clinical trials and controlled studies leading to clinical application and evidence-based guidelines.

Clinical Implementation (T3)
The clinical implementation stage of translation involves adopting interventions that are helpful in a research environment and incorporating them into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.

Public Health (T4)
In this translation stage, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose, and treat them. Findings help guide scientists working to assess current interventions' effects and develop new ones.

Appendix 2. CTS Research Program Budget Request Guide

CATEGORY OF EXPENSE	ALLOWABLE REQUEST ON PILOT PROJECT?
Books, Subscriptions	No
Computers, Laptops	No
Consultative Services	No
Equipment	No
Expenses in Obtaining a Visa	No
Graphics, Photography Charges	No
Indirect Costs	Will be added by the CTSA administrative office in accordance with the negotiated F&A rate agreement
Lab Tests - Clinical	Yes, justify and verify the costs with the laboratory
Lab Tests – Research –Core Services	Yes, justify and verify the costs with the laboratory
Malpractice Insurance	No
Membership Dues	No
Office supplies	No
Parking Fees	No
Personnel Recruitment	No
Publication Costs and Reprints	No
Receptions and Meals	No
Scientific Meeting Fees and Expenses	No
Service Contracts for Equipment Maintenance	No
Software Packages	Yes, a strong justification is required if unavailable and essential to the project.
Space Alterations and Renovations	No
Stipend for Medical Students	Only if they are research personnel
Subject Participation Reimbursement	Yes
Lab Supplies, Disposables.	Yes, provide detailed justification – it must be relevant to the proposed research and must be "consumed" by the project.
Telephone Long Distance (related to project)	No
Travel	No
Tuition costs	No
Uniforms, Apparel	No

ANY NON_LISTED ITEM OR CATEGORY	Please contact the CTSC office.

Appendix 3. Application Submission Process for Invited Full Proposals

Due date October 1, 2025

The submission deadline is 11:59 PM on October 1, 2025. Only those applicants with approved LOI's will be invited to submit a complete application via the InfoReady Grant Management System.

Submissions must be made by the PI or on behalf of the PI through the PI's InfoReady account.
Submissions made under anyone else's name will not be accepted.

Completeness of Application
Complete applications will consist of:

- The online submission
- eRA Commons username of the PI SPARC Request ID (SRID)
- A short summary of the work directed to the lay public (500 characters)
- Dollar amounts of other support currently available to all investigators
- NIH Biosketches of the PI and all co-investigators
- An active IRB and/or IACUC approval letter (if applicable) is needed. If required, there are no exceptions.
- Letter(s) of reference from the CTSC Core program director or his/her designee documenting the PI's consultation with Core management if a CTSC Core Program is being utilized
- Detailed budget and budget justification. Details must include costs per unit x number of units needed and/or cost per hour and number of hours required. Applications lacking sufficient budgetary detail will be returned to the applicant.
- Research proposal (see details below)
- References and figures may be uploaded as a PDF or Word document in the Appendix section of the application.
- Letter of support from PI's department to ensure the investigators have sufficient protected research time and facilities to conduct the proposed research.
- Failure to submit ALL documents before 11:59 PM EST of the submission date constitutes an incomplete application. Incomplete applications will not be reviewed.

Research Proposal
The research proposal (maximum 5 pages based on Arial font size 11, ½" margins) must be uploaded as a PDF within the application. The research proposal will include:

- Background and significance
- Preliminary studies
- Description of the study hypothesis, design, expected results, expected timeline, and feasibility
- Relevance and benefit to the CTSC/Translational Research and the anticipated results and probability that this project will lead to applications for extramural funding.
- If the study requires IRB approval, include an IRB statement including plans to obtain IRB approval by March 31, 2026, dates of submission and/or approval.

- Has this project been submitted to or received Intellectual Property protection? If yes, do you have a plan to file an invention disclosure? If not, would you like help to learn more?
- Statement whether this project is planned to have any foreign components, MOUs, or sub-awards

F.A.I.R. Principles and Rigor & Reproducibility Standards
The research proposal must demonstrate the use of F.A.I.R. Principles and Rigor & Reproducibility Standards throughout the project. For more information and definitions, review the Nature article: The FAIR Guiding Principles for scientific data management and stewardship and NIH's Policy and Compliance website: Enhancing Reproducibility through Rigor and Transparency.

Upload the Research Proposal into the application as a PDF document. The appendix is limited to 5 pages. No abstracts.

Funding decisions will be made on or about December 15, 2025. Any applications with IRBs must have IRB approval IN PLACE prior to March 31, 2026.

Review Process – Application
- All awards that will involve "Applicable Clinical Trials" must register on clinicaltrials.gov before enrollment in the first subject. For additional information about registering for clinical trials, visit: http://prsinfo.clinicaltrials.gov/fdaaa.html
- Recipients of the pilot awards must adhere to Federal, State, and local guidelines concerning scientific conduct of research, conflict of interest policies, human subject participation, and use of animals, hazardous or radioactive materials, and recombinant DNA in their research studies.
- The CTSC Scientific Review Committee (SRC) will review proposals. When appropriate, external experts/reviewers will be asked to participate in the review process by the CTSC SRC.
- Reviewers will rate the proposal according to the NIH Scoring Scale and provide comments as appropriate to the Committee via InfoReady.

In making a decision, the SRC will take into consideration the following:
1. Importance of the Research: a) How well are the aims of the project and the overall project aligned with the overall aims of the CTSC? b) What is innovative about applying technology or technology itself that is relevant to underserved populations? c) What is the potential of the proposed research to promote health equity?
2. Feasibility and Rigor: a) What is the likelihood that the methods, as described, will allow the team to achieve the stated aims? b) To what degree are key stakeholders likely to benefit from the proposed research engaged in the project, including clinicians, patients, community leaders, etc.?
3. Expertise and Resources: a) Does the principal investigator have the necessary experience and expertise to successfully lead the proposed project in achieving its aims? b) Does the project team engage more than one CTSC partner? c) Is the project team multidisciplinary and diverse, including individuals with different types of expertise, backgrounds, and experience?
4. Dissemination/Plans: a) Does the proposal clearly describe how results will be disseminated? b) Does the proposal describe a plan for future research based on the anticipated results of the project?

However, the proposal defines the likelihood that the outcome will lead to subsequent funding or success.

The review committee would like to emphasize the importance of (a) providing a plan for CTSC resource use or enhancement; (b) specifying plans for how the project will lead to funding from other federal and non-federal granting agencies.

Proposals will be reviewed and either approved or disapproved. All applicants receive feedback from blinded peer reviewers. Disapproved projects should take advantage of CTSC services and consider applying for another CTSC funding mechanism.

Appendix 4. Requirements from NIH-NCATS for the CTS Research Program

IRB and IACUC Approvals: All IRB and IACUC protocols must be approved before the expenditure of funds. Any applications with IRBs must have IRB approval IN PLACE prior to March 31, 2026.

Delayed Onset Human Subjects Research: The NIH requires that the CTSC obtain explicit approval from the NIH for any pilot-funded research involving human subjects. Accordingly, the IRB-approved protocol and other materials must be submitted to the NIH at least 45 days before the project start date. CTSC personnel will work with awardees to meet these requirements.

Prior Approval of Vertebrate Animals Research: The NIH requires that the CTSC obtain explicit approval from the NIH for any pilot-funded research involving vertebrate animals. IACUC approval documentation and other materials must be submitted to the NIH at least 45 days before the project start date. CTSC personnel will work with awardees to meet these requirements.

Use of Application Information
The CTSC will not distribute information about submitted proposals to anyone without the applicant's permission except those assigned to review the application. However, the CTSC may ask the applicants for permission to use the title of their application and/or the lay summary for promotional purposes. Permission will be obtained in writing and applicants have the right to decline if they choose. Please contact Rachael Massey at rachael.massey@uhhospitals.org with any questions about this.

Appendix 5. Expectations of awardee

Reporting

1. Awardees must submit an interim report at 6 months and a final report no later than 60 days after the award end date that summarizes major activities and research findings. The CTS Research Program will also contact the awardees on an annual basis (or more frequently as NIH requirements dictate) to request information concerning the funding status of the research initiated with the CTSC award as well as related publications for ten years after the end of the funding period or until the line of research has concluded.
2. Awardees may be asked to present their findings at an annual CTSA retreat.

Publications

3. A copy of any manuscripts or abstracts accepted for publication/presentation containing any results found using funds from the CTSC should be sent to Anna Thornton Matos (abt11@case.edu), CTSC Pilot Program Director, upon notification of acceptance.
4. Support from the CTSC MUST be acknowledged when findings are reported, published, or when publicity is given to the work. All pilot award recipients must agree in writing to cite the CTSC award on all publications resulting from funds from the CTSC to the investigator, making it possible to publish. Please include the following text: "This project was supported by the Clinical and Translational Science Collaborative of Northern Ohio which is funded by the National Institutes of Health, National Center for Advancing Translational Sciences, Clinical and Translational Science Award grant, UM1TR004528. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH." It is imperative to note that ALL publications resulting from this award obtain a PMCID as mandated by the NIH's public access policy.

   Any current or past awardee that does not acknowledge publications and research resulting from this award will not be eligible for future funding or support from the CTSC.

5. Public Access Policy Reminder – The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

Patents

6. Awards are made with the understanding that the CTSC will receive written notification of the filing of a patent application for any discovery made based on work funded by these awards.

Data Sharing

7. In accordance with NIH policy, all primary research data generated with CTSC support will be available for sharing no later than the acceptance for publication of the main findings from the final data set. Even if primary research data are stripped of all personal identifiers, it is possible for deductive disclosure of subjects with unusual characteristics. Therefore, in order to maintain privacy (per HIPAA), data and associated documentation will be available only under a data-sharing agreement that provides for: 1. a commitment to using the data only for research purposes and to NOT identifying any individual participant; 2. a commitment to securing the data using appropriate computer technology; and 3. a commitment to destroying or returning all data after analyses are complete. The data-sharing agreement will also require acknowledgment of the CTSC as the data source and request a pre-release review of any presentations or publications by the CTSC PI (or the PI who generated the primary data). An agreement to provide financial support for itemized specific expenses of data sharing may also be required in the data sharing agreement.

Service as a Reviewer

8. Awardees will be included in a list of researchers as potential reviewers on future CTSC Pilot Grants. Depending upon your specialty and area of expertise, you may be contacted by the Pilot Program Director to review applications.
9. Awardees will be invited to participate in CTSC events and engagements and give presentations.