

2024 Annual Pilot Program RFA
Clinical and Translational Pilot Award Program (NIH UM1TR004528)

The program seeks letters of intent for one-year Annual Pilot Projects (\$50,000) for:

- **Dissemination & Implementation of research evidence and innovation to Clinical Practice**
- **Interventions at Community and/or Clinical Practices to promote Health Equity**

In other words, the later stages of Translational Research are the target. Please see appendix 4.

Applicants will submit a letter of intent to clearly enunciate the proposed activities that address one or more of these goals with a sustainable design for future application to community health. Applicants submitting a successful LOI will be invited to submit a full proposal.

A minimum of two (2), and up to (6) grants, will be awarded with budgets of up to \$50,000 each in direct costs. All research activities must be completed by June 30, 2025.

The ideal letter of intent will address a later stage of clinical research (T3/T4) of community health with an articulated, quantitative outcome result leading to a change in health using Translational Research approaches. Examples which will be more favorably reviewed are:

- Team building across biological and behavioral methodology and clinical health science
- Articulate the innovation for the applicant and/or the co-investigator(s)
- Use community engagement principles to address equity in deployment of the outcomes
- Incremental impact, if any, of a novel strategy to improve health in special populations (e.g. children, minorities, handicapped, elderly, vulnerable...etc.)

Eligibility and Review Criteria

1. We encourage MPI model for these submission. The PI(s) must be a full-time faculty member (or the equivalent) from Case Western Reserve University (CWRU), Cleveland Clinic, MetroHealth Medical Center, University Hospitals, or Louis Stokes Cleveland VA Medical Center and eligible to be a PI for a NIH grant. Co-I's may include faculty at University of Toledo and NEOMED, community health leaders, trainees, and coordinators.
2. **All applications must include 2 or more CTSC partner institutions or they will not be considered for funding**

Scholars currently enrolled in the KL2 Clinical Scholar Program are encouraged to apply. All CWRU Schools may apply for this Northeast Ohio community-directed translational health initiative. Applications from individuals of under-represented minorities are highly encouraged.

More than one proposal per faculty member serving as a co-investigator may be submitted; however, if the LOIs are accepted, conflicts must be addressed in the best interests of the CTSC program goals.



Budget Considerations

Case Western Reserve University will serve as the fiscal entity through which CTSC and/or CTSC/Case Coulter Translational Research partnership funds for technology transfer will be distributed and administered. The amount of the pilot award can be lower, dependent on the scope and type of the project, and proposals can identify opportunity for new supplement funds from additional institutional, departmental, or private funds.

A maximum of \$5,000 in salary support for each investigator can be requested. Budget for supplies and investigative purposes must be well justified. No funds will be provided for administrative assistance, office equipment and supplies, computers, tuition, travel, purchasing and binding of periodicals and books, dues and membership fees in scientific societies, honoraria and travel expenses for visiting lecturers, recruiting and relocation expenses for faculty or staff, office and laboratory furniture, rental of office or laboratory space, per diem charges for hospital beds, non-medical or personnel services to patients, construction or building maintenance, or major alterations.

Number of PIs

One CWRU investigator will be the responsible PI and may only receive one award in the budget year. Additional collaborating investigators will be named. Co-PIs can be listed but cannot be the fiscal contact. If awarded an Annual Pilot, you are ineligible to receive another Annual Pilot for at least two years.

New Investigators

For the purpose of this RFA, a new investigator is defined as a faculty member who is not tenured and who has not been a faculty member at Case or any other institutions for more than six years in aggregate. The review panel can assign extra weight to a proposal from a new investigator to enhance opportunity for funding.

Trans-Disciplinary and Trans-Institutional Team Science

Including co-investigators with diverse skills from different schools, colleges or community organizations is required. A project where one of the investigators is simply providing access (to data, specimens, or patients) is less acceptable than one where there is knowledge or skill sets enhance the Annual Pilot and leads to building a Team for continuation of the theme. *Remember, all applications must include 2 or more CTSC partner institutions or they will not be considered for funding.*

Utilization of a CTSC Core Facility

If a CTSC Core is utilized, detailed documented consultation from the specific CTSC Core director or his/her designee for that CTSC Core is required. Justification for use of the CTSC core(s) must be included in the LOI. Applicants can apply for both an Annual Pilot (\$50,000) and a Core Utilization Pilot (\$10,000 from the PI home institution) if a CTSC Core is being used. The Core Utilization Award however is for 6 months.

Change of Institutions/Transfers

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



Clinical and Translational Science Collaborative and Case Coulter Translational Research Partnership Funding

The CTSC and CCTRP may provide joint funding to faculty for Annual Pilot Projects that will support inter-institutional, clinical and/or technological translational research in the City of Cleveland. CTSC/CCTRP projects are expected to have a Biomedical Engineering faculty member as an integral Co-Investigator. If you have questions about the CCTRP funding, please contact our office.

Submission Process:

Investigators interested in submitting applications to the Annual Pilot Program must first submit a **Letter of Intent (LOI)** to the CTSC Scientific Review Committee (SRC). Investigators submitting a proposal appropriate to the goals of the Annual Pilot Grant Program will be invited to submit a full application.

The LOI is a short summary of the proposal (one page maximum) that must address the following:

- Title and specific Project site(s) as Header
- Names/affiliations of PI, Co-PIs, Co-Investigators and collaborators and a statement of how the award funds would be utilized and distributed
- A brief, focused project summary.
 - Question/Hypothesis of the study – This section should be about ¼ of a page and should describe the overall health related goal addressed by the hypothesis/premise/scientific question. The one-year 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 and describe how your project fills a critical translational gap, and a discussion of anticipated results.
 - Feasibility - This section should be about ¼ of a page and describe the feasible elements of your one-year study. potential roadblocks or concerns in this section. An approved or nearly approved IRB will be favorably received.
 - Project Milestones – This should describe the project plan in about ¼ page. For the scope of this project we suggest no more than 3 temporal or decision-making milestones that can be achieved with the budget allowed (up to \$50,000) and in the time frame selected (up to one year). Please include an estimate of how long each milestone will take, and why it is critical, to the proposal and any long-term plans.
 - Statement as to why this is innovative late Translational Science

Submit the LOI via InfoReady by the deadline of 11:59 pm on November 15th. A decision will be communicated on or about December 15th informing applicants about the LOI results and inviting successful applicants 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) should be due on February 15th. Decisions will be made on or about March 15, 2024. The CTSC leadership and the NIH must review successful applications with IRB approval prior to a start date of July 1, 2024.

Appendix 1. Application Submission Process for Invited Proposals/due date February 15, 2024.

The submission deadline is 11:59pm on February 15th. **Only those applicants with approved LOI's will be invited to submit a full application via the InfoReady Grant Management System.**

Submissions must be made by the PI or on behalf of the PI through 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)
- 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
- Active IRB and/or IACUC approval letter (if applicable). **If required, no exceptions.**
- Letter(s) of reference from 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 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.

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



Review Process – Application

- All awards that will involve “Applicable Clinical Trials” are required to register on clinicaltrials.gov before enrollment of the first subject. For additional information about registering clinical trials visit: <http://prsinfo.clinicaltrials.gov/fdaaa.html>
- Recipients of the pilot awards must adhere to Federal, State, and local guidelines with respect to 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 SRC will review proposals. When appropriate, external 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 Committee will take into consideration the following with the heaviest weighting given to items 1-5.

1. Overall rating of the proposal.
2. Significance, originality, scientific merit and late translational nature of the proposed project.
3. Feasibility, the ability to perform the proposed research within the timeframe allotted.
4. Likelihood that completion will provide the basis for future successful funding and/or operational success within the CTSA framework
5. **Meets the NCATS requirement that supports technology and methodologies with the potential to impact human health.**
6. Budget justification.
7. Partnership goals of the proposal in regard to inter-institutional, inter-departmental and inter-generational partnerships.

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 may be re-submitted to the next Annual Pilot Grant Period.





Appendix 2. Requirements from NIH-NCATS for the CTSC Pilot Program

IRB and IACUC Approvals: All IRB and IACUC protocols must be approved prior to expenditure of funds.

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 prior to 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 prior to 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 to the individuals 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 so choose. Please contact Rachael Massey at rachael.massey@uhhospitals.org with any questions you may have about this.

Service as a Reviewer

Awardees will be included in a list of researchers to serve 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.



Appendix 3. Reporting Process

Grantees are required to 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 CTSC Pilot Grant 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 a period of ten years after the end of the funding period or until the line of research has concluded. Awardees may be asked to present their findings at an annual CTSA retreat.

Publications

A copy of any manuscripts or abstracts accepted for publication/presentation, which contains any results found using funds from the CTSC should be sent to Katie Burke, CTSC Pilot Program Coordinator upon notification of acceptance.

Support from the CTSC **MUST** be acknowledged when findings are reported, published or 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 provided 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 PMID as mandated by the NIH’s public access policy.

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

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 for them 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

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

In accord 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 acknowledgement of the CTSC as the source of data and will request pre-release review of any presentations or publications by the CTSC PI (or the PI who generated the primary data). Agreement to provide financial support for itemized specific expenses of data sharing may also be required in the data sharing agreement.

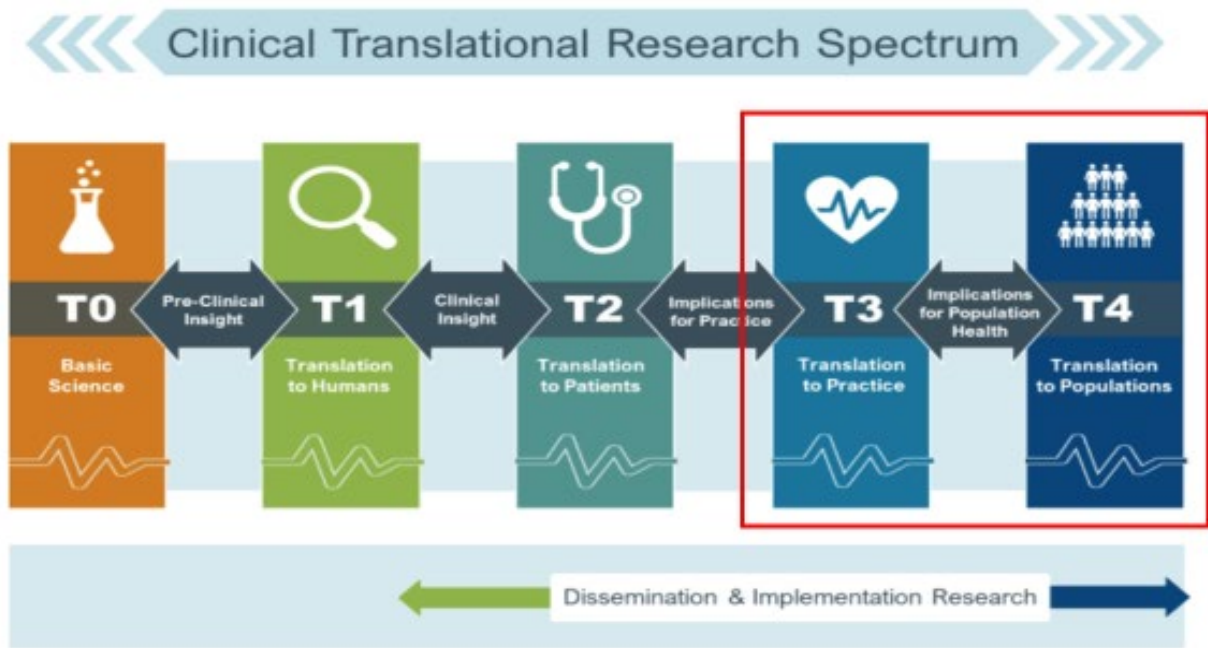


U.S. Department of Veterans Affairs
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Appendix 4. Translational Research Types:

<https://research.musc.edu/resources/sctr/programs/disc>



Basic Research (T0), Pre-Clinical Research (T1), Clinical Research (T2) are NOT the focus for the 2024 Annual Pilot Award.

The areas for funding include:
Clinical Implementation (T3)

The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment 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 stage of translation, 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 the effects of current interventions and to develop new ones.





Appendix 5. Annual Pilot Budget Requests 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 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
Personnel:	
Principal Investigator/ Co-investigator Salary /Fringes	Maximum of \$5,000 (before fringe benefit costs) in salary support of each investigator. Note: established investigators are ineligible for this support
External Employee	No
Technical Support Personnel (study coordinator, lab tech, nurse, procedure tech, student)	Yes, up to \$20,000/year (before fringe benefit costs) to support research assistants or personnel
Publication Costs and Reprints	No
Receptions and Meals	No
Scientific Meeting Fees and Expenses	No
Service Contracts for Equipment Maintenance	No
Software Packages	Yes, if unavailable and essential to the project/strong justification required.
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 – must be relevant to the proposed research and must be “consumed” by the project.
Telephone Long Distance (related to project)	No
Travel – Domestic or Foreign	No





Tuition Costs	No
Uniforms, Wearing Apparel	No
ANY NON-LISTED ITEM OR CATEGORY	Please contact the CTSC office.



U.S. Department of Veterans Affairs
Veterans Health Administration
VA Northeast Ohio Healthcare System