2023 Annual Pilot Program RFA from the Clinical and Translational Pilot Award Program (NIH UL1 TR002548). There is a 2-page introduction for the LOI and 5 Appendices.

Please note, 2023 Annual Pilot grants are contingent upon the CTSC's NIH grant renewal. The CTSC will be notified of the renewal towards the end of May 2023. Annual Pilot grants would be able to begin on or around July 1, 2023.

The program seeks letters of intent for one-year Pilot Projects ($50,000) for **"the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public".** A minimum of two (2) grants, but up to six (6) awards, will be awarded with budgets limited to $50,000 in direct costs. Research proposed in the application must be accomplished by June 30, 2024.

A successful letter of intent would have **applicants clearly enunciate the proposed activities that move "observations/associations" towards "patient/person-centric outcomes". Proposals can be anywhere along the academic spectrum but must include a clinical or health community activist as guiding-light.**

Eligibility and Criteria for Review
The PI is required to be a CWRU full-time faculty member (or the equivalent) from CWRU, Cleveland Clinic, MetroHealth, University Hospitals, or Louis Stokes Cleveland VA Medical Center and eligible to be a PI for a NIH grant. Co-I's may include community health leaders.

Scholars currently enrolled in the KL2 Clinical Scholar Program are encouraged to apply. Applications from individuals of under-represented minorities are highly encouraged.

The letter of intent beyond clearly addressing a premise with an articulated, quantitative health outcome result will be more favorably reviewed if the following criteria are touched in the LOI and the application:

- Team building across biological and behavioral methodology and clinical health science
- Potential to address one or more critical questions in a relatively short span of time
- Articulate the qualifications in research or innovation for the applicant and/or the co-investigator(s)
- Use community engagement principles to address equality in deployment of the outcomes
- Impact if any on special populations (e.g. children, minorities, elderly, vulnerable…etc.)

Budget Considerations
Case Western Reserve University will serve as the fiscal entity through which CTSC and C T S C / Case Coulter Translational Research partnership funds will be distributed and administered. The amount of the pilot award will be dependent on the scope and type of the project. Awards may involve the incorporation of novel methodologies, technology or programming for translational studies and use of CTSC resources. Awardees are encouraged to supplement awards with additional institutional, departmental, or private funds.

Maximum of $5,000 in salary support for each investigator (must be at least two interdisciplinary investigators). Budget must be well justified. **No funds will be provided** for administrative personnel, 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, 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
Only one investigator can be named as PI and may only receive one award in the budget year. Additional collaborating investigators will be named as co- investigators. Co-PIs are not permitted. 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 Team Science
Applicant should consider including co-investigators from different schools or colleges or institutions. A proposal solely bases in one Division or Department will not be as favorably viewed. 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 that enhance the research.

Utilization of 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 should apply for both an Annual Pilot and Core Utilization Pilot if a CTSC Core is being used.

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 program goals.

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 of 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 include the following:

- Title and Project site(s)
- Names/affiliations of PI, Co-Investigators and collaborators

- A brief overview of the project and how the award funds would be utilized and distributed.
    - 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.
    - 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.
    - Project Milestones – This should describe the project plan in about ¼ page. For the scope of this project we suggest 2-3 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 development of the proposal.

Submit the LOI via InfoReady with a deadline of 11:59pm on October 31st. A decision will be communicated by December 15th.

Appendix 1. Application Submission Process for Invited Proposals/due date February 15, 2023.

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 a plan for and probability that this project will lead to 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 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 Ellen Divoky, emd8@case.edu 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 publication was made possible by the Clinical and Translational Science Collaborative of Cleveland, UL1TR0002548 from the National Center for Advancing Translational Sciences (NCATS) component of the National Institutes of Health and NIH roadmap for Medical Research. Its contents are solely the responsibility of the authors and do 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 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.

Appendix 4. Translational Research Types:

Basic Research

Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. Every stage of the translational research spectrum builds upon and informs basic research. NCATS scientists typically do not conduct basic research; however, insights gained from the Center's studies along the translational spectrum can inform basic research.

Pre-Clinical Research

Pre-clinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.

Clinical Research

Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.

Clinical Implementation

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

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.