Annual Pilot Program RFA

The Clinical and Translational Science Collaborative (CTSC) Annual Pilot Award is a NIH funded award to catalyze translation of discoveries to treatments and to develop approaches and methods to provide insights that could be generalizable/scalable to other projects. Such research would advance translational science, the discipline focused on understanding and addressing the scientific and organizational challenges underlying each stage of the translational process. Pilot studies funded under the CTSC pilot program should focus on translational and clinical research rather than on basic discovery research. Special consideration will be given to those proposals that align with specific aims of the CTSC and NCATS and could be implemented throughout the CTSA network. These include creating new opportunities for clinical/translational research at the CTSC.

Applications that are most responsive to this FOA will meet at least one of the following three criteria, as appropriate for this award:

- Develop new methods and/or insights that are generalizable/scalable.
- Involve cross-institutional collaboration between investigators and/or trainees at CWRU and partner institutions.
- Have a high likelihood of leading to a strong extramural peer-reviewed grant application.

Because the mission of NCATS and the CTSA program is disease-agnostic, CTSA funds cannot be used to offset the cost for disease-oriented research studies. An important operational principle of NCATS programs, as opposed to disease-specific NIH Institutes, is to maximize the impact via a catalytic approach: developing, demonstrating utility of, and then disseminating improvements in translational research and operations. The CTSA support should focus on providing a foundation that promotes quality, efficiency, collaboration, and ultimately success as defined by impact. This support should also be used to identify roadblocks and to foster innovation to overcome them. Administrative costs should be carefully considered and justified. Examples of appropriate funding requests may include a limited number of experienced research professionals who can provide oversight, consultations, education, serve as liaison between different partners, help with quality control and assurance, and promote innovation.

Clinical and Translational Science Collaborative and Case Coulter Translational Partnership Funding

The mission of the joint CTSC and the CCTRP pilot funding is to transform translational research not only by providing funding, but also by promoting basic and clinical investigator collaboration, increasing effective collaborations between biomedical engineers and clinicians, supporting the movement of promising technologies to clinical application, providing access to valuable core technologies and services in a collaborative and service-oriented fashion, and to enhance the Team Science* approach to conducting research.

The CTSC and CCTRP will provide joint funding to faculty in multidisciplinary programs for Annual Pilot Projects that will lead to efficient use of resources and support of inter-institutional, clinical translational research in the City of Cleveland. Priorities of the program are to facilitate development of enabling technologies, new therapeutic, diagnostic or outcomes assessment approaches and/or devices, novel cross-disciplinary collaborative programs, and promote research in the community. Thus, research which envisions or creates a stronger potential for intellectual property is encouraged.

CTSC/CCTRP projects are expected to have a Biomedical Engineering faculty member as a Co-Investigator.

* Team Science is a collaborative and multidisciplinary research effort that joins together researchers to explore a specific research problem with specific targeted goals. Team Science collaborations can join together individuals from departments, other institutions, community organizations, and/or other organizations that typically do not interact with one another.
Funding

Funding for the Annual Pilot Grant Awards will be granted by both the CTSC and CCTRP (when qualified for CCTRP funding). Grants will be awarded in the annual funding cycle as CTSA grant funds permit. The CTSC and CTSC/CCTRP Annual Pilot Awards will provide up to $50,000, and may be requested for up to 1 year of support.

Case Western Reserve University will serve as the fiscal entity through which CTSC and CTSC/CCTRP 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 for translational studies and use of CTSC resources. Awardees are encouraged to supplement awards with additional private and institutional 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 secretarial 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.

More than one proposal per faculty member serving as a co-investigator may be submitted; however, a faculty member is only eligible to receive one award as a co-investigator.

Carry-over of funds is not allowed. Proposed projects must be completed in 1 year. The grant period will be from June 1 of the fiscal funding year to May 31 of the following year. This may be subject to change contingent on future funding of our NCATS award.

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 within any funding year.

Application Submission Process

Letter of Intent
Submit online at: http://webgrants.case.edu
The submission deadline is 11:59pm on September 15th (or the first following Monday if September 15th falls on a Saturday or Sunday)

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). The SRC will review all LOIs to determine if the proposed research aligns with the aims of the Annual Pilot Grant Program. Investigators submitting a proposal appropriate to the goals of the Annual Pilot Grant Program will be invited to submit a full application. The letter should include a brief description of your anticipated project, names of project co-investigator(s), collaborator(s), and/or mentor(s), how you fit eligibility criteria (see above), and your contact information (include email address).

A Letter of Intent (LOI) will consist of:
- The on-line submission
- List of all co-investigators
- Brief description of the of the work (<600 words) to include:
  - Scientific Questions/Hypothesis of the study
  - Rationale
  - Methods
A brief overview of the budget to include information of how the award funds would be utilized and distributed. (<200 words)

**Application Submission**
Submit online at: [http://webgrants.case.edu](http://webgrants.case.edu)
The submission deadline is 11:59pm on November 15th (or the first following Monday if November 15th falls on a Saturday or Sunday). **Only those applicants with approved LOI's will be invited to submit a full application.**

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

**Principal Investigator Credentials**
The PI is required to be a full-time faculty member (or the equivalent) from Case Western Reserve University, Cleveland Clinic, MetroHealth, University Hospitals, or Louis Stokes Cleveland VA Medical Center and eligible to be a PI for a NIH grant.

**Number of PIs**
Only one investigator can be named as PI. Additional collaborating investigators will be named as co-investigators. Co-PIs are not permitted.

An investigator may be listed as PI or Co-investigator on any number of applications. However, an applicant may only receive one Award as Principal Investigator or co-investigator. If awarded an Annual Pilot, you are ineligible to receive another Annual Pilot for at least two years.

**New Investigators**
Proposals from new investigators are strongly encouraged. For the purpose of this RFA, a new investigator is defined as a faculty member or equivalent 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.

**Inclusion of Co-Investigators**
Application must include co-investigators from different schools or colleges or institutions. If the co-investigators are from the same school, college or institution, they must be from different departments and justification made in the application that the project is indeed interdisciplinary and new. In addition, the proposal must clearly present the intellectual contribution by each investigator. 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 CTSC Core director or his/her designee for each CTSC Core is required. Justification of use of the CTSC core(s) must be included in the research proposal. It is preferred for applicants who have received information concerning Core fees and charges associated with the proposed research to include that information with the application.

**Completeness of Application**
Complete applications will consist of:
- The on-line submission
- eRA commons username of the PI (either in NIH biosketch or your WebGrants account)
- 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) will be entered directly in the Project Summary form (Rich Text Format) of the WebGrants system. The research proposal will include:
- Background
- Description of the study hypothesis, design, expected results, expected timeline, and feasibility
- Relevance and benefit to the CTSC/Translational Research.

Do not upload the Research Proposal into the Appendix section as a PDF document. The Proposal must be entered directly into the Project Summary box. Applications submitted incorrectly will be returned to the applicant for revision. 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](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.
- Proposals will be reviewed by the CTSC SRC. 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 WebGrants.

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 the proposal or some of its elements go beyond a select disease category, a few diseases or specialties, and thus support NCATS mission to catalyze translation of discoveries rather than on basic discovery research.**
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.

**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 Billie Kyriakides, Director of the CTSC Pilot Program 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, 4UL1TR000439 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 who 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.

**New Requirements from NIH-NCATS for the CTSC Pilot Program**

The federal Protection of Human Subjects regulations, recognize that certain research applications may be submitted to a sponsoring agency with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement cannot be described in the application. This situation is referred
to as "delayed onset human subjects' research" in the NIH Supplemental Grant Application Instructions. As noted in the NIH Grants Policy Statement (GPS), after award and prior to the involvement of human subjects, the grantee must submit to the NIH awarding Institute/Center (IC) for approval.

- Documentation such as the scientific protocol or revised research timeline, as required by the funding IC.
- New or revised human subjects section (see the NIH Supplemental Grant Application Instructions that are part of the NIH competing application guide) that clearly describes risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities.
- **New or revised Inclusion Plans for Women, Minorities, and Children, if applicable.**
- **New or revised Inclusion Enrollment report(s), if applicable. (Note: This action would occur in the Inclusion Management System accessible through the eRA Commons).**
- New or revised Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable.
- Certification that Key Personnel have taken appropriate education in protection of human subjects, if not provided previously.
- Certification of Federal-wide Assurance (FWA) (if not previously provided) and IRB approval of the IC approved plans will be required before the newly proposed human subjects activities can begin.

Institutions with award mechanisms that allow them to use a portion of their budget to select and conduct new human subjects research projects ("pilot projects") are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including obtaining prior approval from the institutional IRB.

**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 Billie Kyriakides, Director of the Pilot Program 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.
# Annual Pilot Budget Requests Guide

<table>
<thead>
<tr>
<th>CATEGORY OF EXPENSE</th>
<th>ALLOWABLE REQUEST ON PILOT PROJECT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Books, Subscriptions</td>
<td>No</td>
</tr>
<tr>
<td>Computers, Laptops</td>
<td>No</td>
</tr>
<tr>
<td>Consultative Services</td>
<td>No</td>
</tr>
<tr>
<td>Equipment</td>
<td>No</td>
</tr>
<tr>
<td>Expenses in Obtaining a Visa</td>
<td>No</td>
</tr>
<tr>
<td>Graphics, Photography Charges</td>
<td>No</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>Will be added by the CTSA administrative office in accordance with negotiated F&amp;A rate agreement</td>
</tr>
<tr>
<td>Lab Tests - Clinical</td>
<td>Yes, justify and verify the costs with the laboratory</td>
</tr>
<tr>
<td>Lab Tests – Research –Core Services</td>
<td>Yes, justify and verify the costs with the laboratory</td>
</tr>
<tr>
<td>Malpractice Insurance</td>
<td>No</td>
</tr>
<tr>
<td>Membership Dues</td>
<td>No</td>
</tr>
<tr>
<td>Office supplies</td>
<td>No</td>
</tr>
<tr>
<td>Parking Fees</td>
<td>No</td>
</tr>
<tr>
<td>Personnel Recruitment</td>
<td>No</td>
</tr>
<tr>
<td>Personnel:</td>
<td></td>
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</tbody>
</table>
| 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. |
HOW TO USE “WEBGRANTS”

The CTSC uses WebGrants online application software.

If this is your first time using WebGrants, you will need to register online at http://webgrants.case.edu. Once you have registered, you will receive an email with your user name and password. The registration process can take up to 24 hours, so applicants are strongly advised to register for an account as soon as possible. Last minute registrations are NOT guaranteed to be approved prior to the deadline. Extensions of the deadline will NOT be given for late registrants.

Researchers should start the web-based application process and become familiar with the system one week prior to the submission deadline. The application may be saved and edited without submission.

LETTER OF INTENT INSTRUCTIONS

- Go to WebGrants (http://webgrants.case.edu/)
- Login (If you are a new user, you will need to register first.)
- Click on “Funding Opportunities”
- Click on “CTSC Annual Pilot Grants 2017”
- Click on “Start a New Application”
- Fill in the title of your proposal and Click on “Save”
- Click on “Go to Application Forms”
- Complete the Letter of Intent Form (can do in multiple sessions)
- Once all forms are completed and conform to form instruction, submit your letter of intent no later than September 15th; 11:59pm (or the first following Monday if September 15th falls on a Saturday or Sunday)

FULL APPLICATION INSTRUCTIONS

- Go to WebGrants (http://webgrants.case.edu/)
- Login (If you are a new user, you will need to register first.)
- Click on “Funding Opportunities”
- Click on “CTSC Annual Pilot Grants 2017”
- Click on “Start a New Application”
- Fill in the title of your proposal and Click on “Save”
- Click on “Go to Application Forms”
- Complete all forms (can do in multiple sessions)
- Once all forms are completed and conform to form instruction, submit your application no later than November 15th; 11:59pm (or the first following Monday if November 15th falls on a Saturday or Sunday)

NOTES:

1. For technical questions related to WebGrants, please contact WebGrants support: webgrants-support@case.edu or call 216-368-4669.

2. For non-technical questions regarding this RFA or your application, please contact the CTSC Pilot Program office: CTSC-Pilot-Coordinator@case.edu or call 216-368-0840.

The CTSC Pilot Grant Program strongly encourages applicants to contact the Pilot Grant Coordinator with any questions you may have regarding the application process prior to the submission of the proposal.