### Annual Pilot Purpose

The Clinical and Translational Science Collaborative (CTSC) Annual Pilot Award is a NIH funded internal project/study award to promote the development of novel solutions, methods, and/or processes that will ultimately improve clinical and translational research outcomes as it relates to patients, community health, community, health policy, product development, and interventions. Special consideration will be given to those proposals developing new methods and/or best practices that could be implemented throughout the CTSA network.

The Clinical and Translational Science Collaborative (CTSC) and the Case Coulter Translational Research Partnership (CCTR) seek to support innovative translational research projects focused upon the invention, preclinical development and/or first in man studies of novel therapeutic agents, biomedical devices and diagnostics designed to address unmet clinical needs. The mission of the CTSC and the CCTRP pilot program 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 seed money to faculty in multidisciplinary programs for 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.

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`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.`

### New Requirements from NIH-NCATS for the CTSC Pilot Program!

**Notification from NIH-NCATS regarding CTSA Pilot Funding**

Each CTSA hub has the flexibility to focus and design their translational pilot program to address their particular priorities; however, the program will no longer support a focus solely on a select disease category, a few diseases or specialties, or on a limited number of investigators. The pilot studies funded under the CTSA program should focus on translational and clinical research rather than on basic discovery research. In keeping with the NCATS mission to catalyze in general the translation of discoveries to treatments. A preferred, but not required, characteristic would include an effort to provide insights that could be generalizable across the research spectrum. Such research would advance translational science, understanding and addressing the scientific and/or organizational challenges underlying each stage of translational medicine.

**Because the mission of NCATS and the CTSA program is disease-agnostic, CTSA funds can therefore not be used to offset the cost for a necessarily select set of disease-oriented research studies.** As a general principle, therefore, the CTSA funding should be used to facilitate and catalyze research supported by other funders (with the exception of those pilot and collaborative studies that are funded by the CTSA program itself). 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 science and operations. The CTSA support should thus 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, but who cannot provide the actual research procedures.

**NCATS can develop and provide infrastructure and resources for all phases of clinical trials, but it can directly support clinical trials only through the end of phase II A.**

### Scope of Proposals

The pilot studies should focus on translational and clinical research rather than on basic discovery research. A preferred, but not required, characteristic would include an effort to provide insights that could be generalizable across the research spectrum. Such research would advance translational science, understanding and addressing the scientific and/or organizational challenges underlying each stage of translational medicine. Preference will be given to proposals representing a new collaboration (inter-institutional or inter-departmental), for translational research consistent with the goals of the CTSC and NCATS, and those which foster a senior/junior relationship. A new collaboration is one where the investigators have never worked together on a research project before.

Proposals simply building on existing collaborations are discouraged unless the proposed project represents a new direction for this collaboration or a substantial innovation. In such a case, the proposal should clearly describe the new direction or the transformative technology proposed by the existing collaboration (see below) and its translational agenda.

While new proposals from young investigators and clinical research scholars (e.g., KL2) are encouraged, proposals in this RFA will also be considered if the award would substantially enhance a current funded pilot project or if the award would provide start-up funding for a proposal to a federal agency for the use of CTSC and CCTRP resources that has been reviewed very positively at a national level. The CTSC and CCTRP welcome proposals that propose interactions among its affiliated institutions or with corporate partners, and the matching of funds that would increase the number or enhance the financing of these awards. Awards to an established investigator will need to have a plan to engage an early career faculty member or investigator who is on a path towards being a clinical scientist and support the movement of promising technologies to clinical application and developing sustainable processes.

The ultimate goal of the CTSC and CCTRP Pilot Award program is to focus on outcomes which will save, extend, and improve patient lives in Northeast Ohio.

### 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 CCTRP Annual Pilot Awards will fund **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 CCTRP monies will be distributed and awards 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.

### Principal Investigator Credentials

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

The Institution of Record will be the PI’s primary institution.

### Number of PI's

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

### New Investigators

Proposals from new investigators are strongly encouraged. For the purposes of this RFP, 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 institution 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 or college or institution, they must be from different departments and a case 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.  

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

<table>
<thead>
<tr>
<th>Letter of Intent</th>
<th>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 matches the aims of the Annual Pilot Grant Program. Investigators submitting proposal appropriate to the goals of the Annual Pilot Grant Program will be invited to submit a full application.</th>
</tr>
</thead>
</table>

| Application Submission | All applications will be submitted through WebGrants, the CTSC’s online grant application. Please see detailed instructions at the end of this document.  

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

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

| Completeness of LOI | A complete letter of intent will consist of:  

- The on-line submission  
- List of all co-investigators  
- Short summary of the of the work (<600 words) to include:  
  - Scientific Questions/Hypothesis of the study  
  - Rationale  
  - Methods  
  - Innovation  
  - Feasibility  
  - Relevance and benefit to the CTSC/Translational Research  
  - Inter-institutional, inter-departmental novel or inter-generational interactions (<200 words)  
  - An overview of the budget to include information of how the award funds would be utilized and distributed. (<200 words)  

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

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

| Completeness of Applications | 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 support currently available to all investigators  
- NIH Biosketches of the PI and all co-investigators  
- Active IRB and/or IACUC approval letter (if applicable)  
- 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  

Only those applicants with approved LOI's will be invited to submit a full application.  

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

**Submission – Full Application**  
Submit online at: [http://webgrants.case.edu](http://webgrants.case.edu)  
The submission deadline is 11:59pm on March 15th (or the first following Monday if March 15th falls on a Saturday or Sunday)  

Only those applicants with approved LOI’s will be invited to submit a full application.
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.

### 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.

### Project Length

Proposed projects must be completed in 1 year. **Carry-over of funds is not allowed.**

Grant period will be from June 1st of the funding year to May 31st of the following year.

### Maximum Award Request

$50,000 maximum total.

Maximum of $5,000 in salary support for each investigator (must be at least two interdisciplinary investigators); however, established investigators are ineligible for this support. Please note fringe benefits are in addition to the $5,000. Budget must be well-justified.

### Funding Restrictions

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.

### Review Process – Letter of Intent

- Letters of Intent will be reviewed by the CTSC SRC.
- Investigators whose proposals meet the requirements of the RFA and reflect the goals of the CTSC Annual Pilot Grant Program will be invited to submit a full application.

### 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, 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:
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<table>
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<tbody>
<tr>
<td>1.</td>
<td>Overall rating of the proposal.</td>
</tr>
<tr>
<td>2.</td>
<td>Significance, originality, scientific merit and translational nature of the proposed project.</td>
</tr>
<tr>
<td>3.</td>
<td>Feasibility, the ability to perform the proposed research within the timeframe allotted.</td>
</tr>
<tr>
<td>4.</td>
<td>Likelihood that completion will provide the basis for future successful funding and/or operational success within the CTSA framework.</td>
</tr>
<tr>
<td>5.</td>
<td><strong>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.</strong></td>
</tr>
<tr>
<td>7.</td>
<td>Partnership goals of the proposal in regard to inter-institutional, inter-departmental and inter-generational partnerships.</td>
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</table>

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.

### Re-submissions

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.

### Multiple Awards

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.

### Reporting Process

Grantees are required to submit an interim report at 6 months and a final report at the completion of the award summarizing major activities and research findings. The CTSC Pilot Grant Program will also contact the awardees on an annual basis, or more often as NIH requirements dictate, to request information concerning the funding status of the research initiated with the grant 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.

### 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.

### Re-budgeting

Funds may be re-budgeted with documented justification and approval by the CTSC Governance and Administration Core. Budgeted Pilot funds may never be transferred to another Pilot project, activity account or research project.

### Change of Principal Investigator

A change of PI is not allowed. Award transfer to another institution outside of CTSC is not allowed.

### Citation Policy

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, UL1TR000439 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.

### 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 the Pilot Grant Coordinator with any questions you may have about this.

### Public Access Policy

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
<p>| Reminder | 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. |</p>
<table>
<thead>
<tr>
<th>CATEGORY OF EXPENSE</th>
<th>ALLOWABLE REQUEST ON PILOT PROJECT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animals and Care</td>
<td>Yes, justify and verify costs with ARC office</td>
</tr>
<tr>
<td>Bioinformatics Charges</td>
<td>Yes, justify and verify costs with Research Informatics</td>
</tr>
<tr>
<td>Books, Subscriptions</td>
<td>No</td>
</tr>
<tr>
<td>Biostatistics Charges</td>
<td>Yes, justify and verify costs with Biostatistics</td>
</tr>
<tr>
<td>Computers, Laptops</td>
<td>No</td>
</tr>
<tr>
<td>Consultative Services</td>
<td>No external consultants</td>
</tr>
<tr>
<td>Equipment</td>
<td>Minor equipment (under $5000) with justification that the equipment is not available at Institution and essential to the project</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, general</td>
<td>No, this is same as indirects</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>
</tr>
<tr>
<td>Principal Investigator/ Co-investigator</td>
<td>Maximum of $5,000 (before fringe benefit costs) in salary support for each investigator however, established investigators are ineligible for this support</td>
</tr>
<tr>
<td>Salary / Fringes</td>
<td></td>
</tr>
<tr>
<td>External, non-CTSC Institution Employee</td>
<td>No</td>
</tr>
<tr>
<td>Technical Support Personnel (study</td>
<td>Yes, up to $20,000/year (before fringe costs) to support research assistants or personnel</td>
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<tr>
<td>coordinator, lab tech, nurse, procedure</td>
<td></td>
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<tr>
<td>tech, student)</td>
<td></td>
</tr>
<tr>
<td>Publication Costs and Reprints</td>
<td>No</td>
</tr>
<tr>
<td>Receptions and Meals</td>
<td>No</td>
</tr>
<tr>
<td>Scientific Meeting Fees and Expenses</td>
<td>No</td>
</tr>
<tr>
<td>Service Contracts for Equipment</td>
<td>No</td>
</tr>
<tr>
<td>Maintenance</td>
<td></td>
</tr>
<tr>
<td>Software Packages</td>
<td>Yes, if unavailable and essential to the project/strong justification required.</td>
</tr>
<tr>
<td>Space Alterations and Renovations</td>
<td>No</td>
</tr>
<tr>
<td>Stipend for Medical Students</td>
<td>Only if they are research personnel</td>
</tr>
<tr>
<td>Subject Participation Reimbursement</td>
<td>Yes</td>
</tr>
<tr>
<td>Lab Supplies, Disposables</td>
<td>Yes, provide detailed justification – must be relevant to the proposed research and must be “consumed” by the project.</td>
</tr>
<tr>
<td>Telephone Long Distance (related to project)</td>
<td>No</td>
</tr>
<tr>
<td>Travel – Domestic or Foreign</td>
<td>No</td>
</tr>
<tr>
<td>Tuition Costs</td>
<td>No</td>
</tr>
<tr>
<td>Uniforms, Wearing Apparel</td>
<td>No</td>
</tr>
<tr>
<td>ANY NON-LISTED ITEM OR CATEGORY</td>
<td>Please contact the CTSC office.</td>
</tr>
</tbody>
</table>
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 2016”
• 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 January 15th; 11:59pm (or the first following Monday if January 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 2016”
• 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 March 15th; 11:59pm (or the first following Monday if March 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. Applications that are incomplete or incorrect will be returned to the applicant for revision.