

Taipei Medical University/Case Western Reserve University Translational Pilot Collaborative

<p>TMU/CWRU Pilot Program Pilot Purpose</p>	<p>Taipei Medical University along with the Clinical and Translational Science Collaborative (CTSC) is pleased to offer a collaborative pilot award opportunity to promote translational research projects through team science*. The objective is to accelerate laboratory discoveries into new treatments and to foster the education of highly skilled scientists and engineers to encourage the next generation of global scientific and engineering leaders. The target areas for funding are Oncology or Biomedical Technology Device and Drug Development. A separate RFA is available for Aging and Models of Care.</p> <p>Taipei Medical University (TMU) and the Clinical and Translational Science Collaborative (CTSC) seeks 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 CWRU/CTSC and TMU 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 physicians, scientists, and engineers, 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 collaborative Team Science* approach to conducting research.</p> <p>The CWRU CTSC and TMU 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. 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. Thus, research that envisions or creates a stronger potential for intellectual property is encouraged. In addition, funded investigators and projects will be paired for collaboration opportunities with TMU investigators where additional funds will be made available on the TMU side. Investigators must be open to and assist in developing relevant international collaborations during the funded award period as a condition of the award. These details will be worked out in the context of award negotiation for investigators recommended for funding after the review process.</p> <p>* 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.</p>
<p>Scope of Proposals</p>	<p>Consideration will be given to proposals representing a new collaboration for translational research or provide opportunities for collaboration with TMU consistent with the goals of TMU and the CTSC. A new collaboration is one where the investigators have never worked together on a research project before. 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 non-federally funded pilot project or if the award would provide start-up funding for a proposal to a federal agency for the use of TMU and CTSC resources that has been reviewed very positively at a national level. TMU and the CTSC 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.</p> <p>The ultimate goal of TMU and the CTSC Pilot Award program is to focus on outcomes which will save, extend, and improve patient lives.</p>
<p>Funding</p>	<p>Funding for these Pilot Awards will be granted by both TMU and the CTSC. Grants will be awarded in the funding cycle as established by TMU and the CTSC. TMU and CTSC Pilot Awards will fund up to \$50,000, and may be requested for up to 1 year of support. Additional support may be awarded in the context of Core Utilization Pilot awards if justified in the proposal.</p> <p>Taipei Medical University and Case Western Reserve University will serve as the fiscal entity through which TMU and CTSC 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.</p>

Principal Investigator Credentials	<p>The PI is required to be a full-time faculty member (or the equivalent) from University Hospitals Cleveland Medical Center, Cleveland Clinic, Case Western Reserve University, MetroHealth Medical Center, and Louis Stokes Cleveland VA Medical Center and eligible to be a PI for an NIH grant. The eligible TMU team member(s) will be selected after the review process is completed.</p> <p>The Institution of Record will be the PI's primary institution.</p>
Number of PI's	<p>Only one investigator can be named as PI. Additional collaborating investigators will be named as co-investigators. Co-PIs are not permitted.</p>
New Investigators	<p>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.</p>
Inclusion of Co-Investigators	<p>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.</p>
Letter of Intent and Full Proposal	<p>Investigators interested in submitting applications to the Taipei/CWRU Pilot Program must first submit a Letter of Intent (LOI) to the Taipei/CWRU Scientific Review Committee (SRC). The SRC will review all LOIs to determine if the proposed research matches the aims of the Taipei/CWRU Pilot Grant Program. Investigators submitting proposal appropriate to the goals of this Pilot Grant Program will be invited to submit a full application. We hope to notify applicants by October 17, 2016 with a deadline for full proposal to be November 7, 2016.</p>
Submission – Letter of Intent	<p>Submit online at: http://webgrants.case.edu The submission deadline is 11:59pm on October 3, 2016.</p>
Completeness of LOI	<p>A complete letter of intent will consist of:</p> <ul style="list-style-type: none"> • The on-line submission • List of all co-investigators • Short summary of the of the work (<300 words) to include: <ul style="list-style-type: none"> ○ Scientific Questions/Hypothesis of the study ○ Rationale ○ Methods ○ Innovation ○ Feasibility ○ Relevance and benefit to the Taipei/CWRU/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)
Application Submission	<p>All applications will be submitted through WebGrants, the CTSC's online grant application. Please see detailed instructions at the end of this document.</p> <p>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.</p> <p>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.</p>
Submission – Full Application	<p>Submit online at: http://webgrants.case.edu The submission deadline is 11:59pm on (November 7, 2016)</p>
Completeness of Applications	<p>Complete applications will consist of:</p> <ul style="list-style-type: none"> • The on-line submission • Short summary of the work directed to the lay public (500 characters) • Dollar amounts of support currently available to all investigators • NIH Biosketches or equivalent 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

	<p>PI's consultation with Core management if a CTSC Core Program is being utilized</p> <ul style="list-style-type: none"> 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. <p>Failure to submit ALL documents before 11:59 pm EST of submission date constitutes an incomplete application. Incomplete applications will not be reviewed.</p>
Research Proposal	<p>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:</p> <ul style="list-style-type: none"> Background Description of the study hypothesis, design, expected results, expected timeline, and feasibility Relevance and benefit to the CTSC/Translational Research. <p>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.</p>
Utilization of Core Facility	<p>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.</p>
Project Length	<p>Proposed projects must be completed in 1 year. Carry-over of funds is not allowed. Grant period to be established</p>
Maximum Award Request	<p>\$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.</p>
Funding Restrictions	<p>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.</p>
Review Process - Application	<ul style="list-style-type: none"> 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, use of animals, hazardous or radioactive materials, and recombinant DNA in their research studies. Proposals will be reviewed by the TMU and CTSC Scientific Review Committee. When appropriate, external reviewers will be asked to participate in the review process by TMU and 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 1-4: <ol style="list-style-type: none"> Overall rating of the proposal. Significance, originality, scientific merit and translational nature of the proposed project. Feasibility, the ability to perform the proposed research within the timeframe allotted. Likelihood that completion will provide the basis for future successful funding and/or operational success within the TMU and CTSA framework

	<p>5. Budget justification.</p> <p>6. Partnership goals of the proposal in regard to inter-institutional, inter-departmental and inter-generational partnerships.</p> <p>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.</p>
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 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.
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 TMU and CTSC Pilot Grant Program will also contact the awardees on an annual basis, or more often as necessary to request information concerning the status of the research initiated and supported with these funds. Reporting of related publications for a period of up to five years is required 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 or other research showcase forum.
Service as a Reviewer	Awardees will be included in a list of researchers to serve as potential reviewers on future TMU and CTSC Pilot Grants. Depending upon your specialty and area of expertise, you may be contacted by the TMU team and/or CTSC Pilot Program Director to review applications.
Re-budgeting	Funds may be re-budgeted with documented justification and approval by the TMU and CTSC executive leadership will be required prior to the actual reallocation of funds. Scope of work cannot be changed. 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 TMU and the CTSC is not allowed.
Citation Policy	All pilot award recipients must agree in writing to cite TMU and the CTSC award on all publications resulting from the research supported through funds provided from TMU and the CTSC. Please include the following text: "This publication was made possible by the Taipei Medical University 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."
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, TMU and 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.

Pilot Budget Requests – Allowable Budget Items

CATEGORY OF EXPENSE	ALLOWABLE REQUEST ON PILOT PROJECT?
Animals and Care	Yes, justify and verify costs with ARC office
Bioinformatics Charges	Yes, justify and verify costs with Research Informatics
Books, Subscriptions	No
Biostatistics Charges	Yes, justify and verify costs with Biostatistics
Computers, Laptops	No
Consultative Services	No external consultants
Equipment	Minor equipment (under \$5000) with justification that the equipment is not available at Institution and essential to the project
Expenses in Obtaining a Visa	No
Graphics, Photography Charges	No
Indirect Costs	N/A
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, general	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 for each investigator however, established investigators are ineligible for this support
External, non-CTSC Institution Employee	No
Technical Support Personnel (study coordinator, lab tech, nurse, procedure tech, student)	Yes, up to \$20,000/year (before fringe 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 “**TMU/CWRU/CTSC Pilot Award**”
- 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 October 3rd; 11:59pm.**

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 “**TMU/CWRU/CTSC Pilot Award**”
- 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 7th; 11:59pm.**

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.