SCHOOL OF MEDICINE
CASE WESTERN RESERVE
U N I V E R S I T Y

CTSC
Clinical & Translational
Science Collaborative

Request for Applications
CTSC FDA Guidance Core Utilization Pilots
Funded by CTSC Institutional Partners

Purpose of "Core Utilization Pilots"	**This pilot program primarily supports access to the CTSC FDA Guidance Core facility, specifically providing funding to investigators/researchers interested in moving drugs/devices through the pipeline.** The FDA Guidance Core is a comprehensive and standardized resource for investigators who are conducting new drug/new device research with the Food and Drug Administration. Support through the FDA Guidance Core is tailored to the investigators specific needs and can include regulatory document development, risk base monitoring, data management, and long term quality control for the lifecycle of the study. The pilot goals must be clearly intended to support the efforts of a sponsor-investigator study that will ultimately lead to the development of a novel drug/device or to enhance an existing drug/device. Therefore, the PI must be eligible to submit an application to the FDA. Funding priority is given to projects that illustrate: • Pre-clinical safety information available relating to investigational product • Evidence of product testing in pre-clinical environment • Clear ability to complete proposed project within the 6 month funding period • Evidence of sound protocol pathway through the FDA • Project is beyond early product testing/use.
Principal Investigator Credentials	Case Western Reserve University (CWRU), Cleveland Clinic (CC), University Hospitals Cleveland Medical Center (UHCMC), MetroHealth Medical Center (MHMC), CWRU School of Nursing, CWRU School of Dental Medicine and the Louis Stokes Cleveland VA Medical Center (VA) are supporting this program. Primary Investigators whose primary appointments are based at these sites are eligible for this competition. Application of women, individuals with disabilities, and members of underrepresented groups is encouraged. • PI must have a faculty appointment (or equivalent) at CWRU, CC, UHCMC, MHMC or VA and must be eligible as principal investigator to submit an application to a larger source of federal or non-federal support. • Only one investigator can be named as PI. Additional collaborating investigators will be named sub-investigators. Co-PIs are not permitted. • The institution of record for a proposal is the PI's primary institution.
Maximum Award Request	Funds for the FDA Guidance Core Utilization Grant are provided directly to the awardees by The CTSA partner institutions. The institution providing the funds will be the PI's primary institution. • **Funds will primarily be spent in the FDA Guidance Core** and secondarily in other eligible cores to support the work in the FDA Guidance Core as appropriate. Budget requests for anything other than core use are not allowed and will be denied. A list of eligible Cores Services may be found on the CTSC website. • Support can be any amount up to a maximum of $10,000. • Detailed budget of core services and budget justification. Details must include costs per unit and 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. If a project requires funds for other than core-use-costs, the investigator will need to seek other funding sources. Institutions, departments or investigators may match funding or provide additional funds.
Project Length	Proposed projects **must be** completed within **six months** of the award date. An extension up to 6 additional months will be considered on a case by case basis.
Submission Method / Submission Deadlines	Applications are to be submitted electronically through **WebGrants** at any time. The FDA Guidance Core Utilization Pilot Grant Program has a monthly deadline format. Applications received by the first of the month will be reviewed and the results returned to the investigator before the 1st of the subsequent month. Applications must be received by 11:59pm EST on the first day of the month. See "How to Use WebGrants" section at end of this document.

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

Completeness of Application / Proposal Requirements	**Complete applications are submitted electronically via WebGrants and must include:**
	
	• A short summary of the work in lay language. The summary should be 5-10 sentences (1000 character limit) and present the essential elements of the proposal. Think of this as your "quick pitch" of the proposed work to the committee.
	
	• Contact information for the PI and all sub-Investigators
	
	• NIH biosketch of the PI and all sub-Investigators who will be decision makers on the trial
	
	• eRA commons username of the PI (either in NIH biosketch or WebGrants account)
	
	• Other Support of PI and sub-Investigator(s)
	
	• Two to four sentences addressing the translational impact of the project. Specifically, how the results of the research will lead to improvements in human health or disease.
	
	• Two to four sentences addressing the applicant's plans on turning the results of a funded proposal into future successes, such as publications, grant submissions, patent submissions, etc.
	
	• <u>Detailed</u> budget of Core services and budget justification. Details must include costs per unit and number of units needed and/or cost per hour and number of hours required. It is preferable for the applicant to provide a letter, when available, from the Core detailing their fees as they pertain to the proposed research. **Applications lacking sufficient budgetary detail will be returned to the applicant.**
	
	• A letter documenting the applicant's consultation with the core director or his/her designee for each core utilized must accompany the application. This is to assure that the core can provide the needed service in a timely manner.
	
	• <u>One-page application</u> (based on Arial, font 11, ½" margins or less than 6000 characters with spaces) may either be entered directly into the Project Summary form of the WebGrants system or attached as a PDF file.
	
	    o Describe the background, study hypothesis, design, expected results, expected timeline and feasibility. The feasibility questions are:
	
	        ▪ Are the samples (data) already in hand, or do they need to be collected?
	
	        ▪ If the pilot data are successful, list any impediments to proposing a subsequent study (e.g., are there a sufficient number of subjects, is there sufficient capacity in CRU or core facilities to handle it, etc.)?
	
	        ▪ To which funding agency will an application for a larger study be submitted?
	
	    o Provide justification of use of the CTSC Core(s)
	
	    o Demonstrate the clinical or translational nature of the research
	
	    o References and figures may be uploaded as a PDF or Word document in the Appendices A and B of the application. ***Please note Appendix A is for any regulatory information and Appendix B is limited to 2 pages of supplemental data.***

Reviewer Process	Applications will be reviewed by the Scientific Review Committee (SRC) of the CTSC. When necessary, the SRC will request the input of other researchers on the basis of their background and experience. Detailed reviews will not be provided to the applicant, but a summary and the sense of the comments will be conveyed to all applicants.
Re-budgeting	Funds may not be re-budgeted for a different eligible Core. Budgeted Pilot funds may never be transferred to another Pilot project, activity account or research project.
Multiple Awards	Any number of applications may be submitted listing an investigator as PI or sub-investigator. However, applicants that have received a Core Utilization award in the past 12 months must provide documentation outlining how the current project differs from the funded proposal. Only those projects that demonstrate a new line of research will be considered.

Completion of Project	Evaluation of progress of a CTSC Pilot award is essential for the success of the awardee/recipient of the pilot funds as well as the overall success of the CTSC. At the close of a project, the PI must submit a report summarizing the results of the project and list of plans for publications, presentations and submission for external grant applications. Final progress report should include the following: • review of specific aims originally proposed • status of enrollment and progress if applicable • publications planned or in process • outcomes of research project/how did this award impact the investigator's overall research • list of all collaborators to include those included in original proposal and those who were not included, but became involved during the research project Final report is due 30 days from project end date Failure to provide this completed report will disqualify the PI for future awards. Updates on publications and extramural funding will be required as necessary. Awardees must provide contact information for up to 10 years following awards as the funding and publication success of recipients must be tracked for our program to secure additional support If the pilot study is successful, it is expected that further studies using the Core facilities will be written into extramural grant applications and further use of Core facilities will be supported from external funds.
Expenditure of Funds	Proposed projects are expected to be accomplished within **six months** of award date unless additional timeline and expenditure have been documented and approved. All funds must be spent by the end of the award date. Invoicing for items other than what appears on the applicant's detailed budget request will not be accepted.
Citation Policy	<u>Citation of the CTSC award is mandatory.</u> 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."**
Change of Principal Investigator / PI Leaving	A change of PI may be formally requested. Award transfer to another institution is not permitted.
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.
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 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.

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.

APPLICATION INSTRUCTIONS
- Go to WebGrants (http://webgrants.case.edu/)
- Login
- If you are a new user, you will need to register first (see above).
- Click on "Funding Opportunities"
- Click on "CTSC FDA Guidance Core Utilization Pilot Grant"
- 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 logout and return to complete in multiple sessions).
- Once all forms are completed and conform to form instructions, "Submit" your application.

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.

Examples of possible applications
- An investigator wishes to compare the proteome of CSF in patients with MS before and after a new treatment intervention. She contacts the CWRU Center for Proteomics and Bioinformatics and subsequently applies for support to measure proteomics of the CSF in three normal subjects and three with MS in order to demonstrate feasibility, identification of proteins of interest, and, possibly, a difference between normal and MS patients. The funds will be spent in the CWRU Center for Proteomics and Bioinformatics.
- An investigator wishes to study imaging techniques in brain cancers. He contacts the Imaging Core Facility and applies for funds to conduct two ordinary MRI scans and two with a new imaging agent to demonstrate feasibility, safety, and possible efficacy. Funds will be spent in the Imaging Core Facility.
- An investigator has collected preliminary data on outcomes in prostate cancer and wishes to perform a data analysis to support his request for additional funding of this study. He contacts the BERD Core and then requests the appropriate funds for statistical work, which will be spent in the BERD.

For additional information on translational research, please visit the Pilot Grant Program section of our website: http://casemed.case.edu/ctsc/cores/pilotgrant.cfm and select "Translational Research and Pilot Funding" from the Quick Links section on the right hand part of the screen.

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.