

Request for Applications
Center for SUDEP Research (CSR)
Funded by CTSC Institutional Partners

<p>SUDEP Pilot Purpose</p>	<p>The Center for Sudden Unexpected Death in Epilepsy (SUDEP) Research seeks novel pilot projects in human SUDEP Research that will address the goal of understanding SUDEP pathophysiology. This pilot program will award a grant to clinician researchers engaged in human research in submitting innovative proposals that specifically utilize the Informatics and Data Analytics Core of the CSR and at the end of the study period will provide study data to this Core for human SUDEP research. The investigators will be expected to commit to this stipulation. Successful applicants will be expected to work collaboratively with the CSR investigators and where possible, make use of available CTSC Core Facilities. We are specifically encouraging applications from human epilepsy, cardiac and respiratory researchers. Clinical researchers with a focus on database analysis may apply as long as the focus is explicitly on SUDEP.</p>
<p>Scope of Proposals</p>	<p>Preference will be given to proposals representing a new collaboration for the Center for SUDEP Research within the local network of the CTSC. This award is available to both young and established investigators exploring cutting-edge approaches to understanding and preventing human SUDEP.</p>
<p>Funding</p>	<p>Funding for the one-year CSR-themed Pilot Grant Award will be granted by the CTSC in collaboration with the Center for SUDEP Research. This opportunity will be an annual event. One (1) \$25,000 will be awarded. Sole usage of funding for salary support of senior investigators is not encouraged. Only \$5,000 + related fringe of the grant can go towards the Principal investigator's (PI) salary, unless the PI is in a field where their intellectual contribution is their research (i.e. Statistician). The PI will be expected to budget for attendance at the American Epilepsy Society meeting, where they will provide a research update on their project</p> <p>In addition, \$10,000 is available for the use of one CTSC Core per pilot grant award when used in support of the primary grant. The core grant funding must be justified within the application budget. Monies may only be used for the in-line items listed in your detailed budget in your application.</p> <p>Case Western Reserve University will serve as the fiscal entity through which the CTSC monies will be distributed and awards administered.</p>

Principal Investigator Eligibility	The PI is required to be a full-time CWRU faculty member with a primary appointment at Case Western Reserve University, University Hospitals Case Medical Center, or the Louis Stokes VA Medical Center.
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. Consultants outside of CWRU are permitted.
New Investigators	Proposals from new investigators are strongly encouraged. For the purposes of this RFA, a new investigator is defined as a faculty member who is not tenured and who has not been a faculty member at Case or any other 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	Applications 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 enhances the research.
Application Submission	<p>All Applications will be submitted through WebGrants, the CTSC's online grant application system. 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.</p> <p>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	Submit online at: http://webgrants.case.edu , due Friday, April 28, 2017 at 11:59 pm, EDT.
Components of Application	<p>Complete applications will consist of:</p> <ul style="list-style-type: none"> • The on-line submission • eRA Commons username of the PI (either in NIH bio sketch or your WebGrants account) • Short Summary of the work directed to the lay public (500 characters) • NIH Bio sketches 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 written budget justification.

	<ul style="list-style-type: none"> • Research proposal (see below) • References and figures may be uploaded as a PDF or Word document (3 page maximum) 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 11:59pm EDT, April 28, 2017 constitutes an incomplete application and will not be reviewed.
Research Proposal	<p>The research proposal (maximum 3 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. Applications should include the following:</p> <p>The research proposal will include:</p> <ul style="list-style-type: none"> • Specific aims (maximum 1 page) • Background and Research Plan (maximum 2 pages) The aims and background/research plan sections should include a description of the study hypothesis, design, expected results, expected timeline, and feasibility • Relevance and benefit to the CTSC/Translational Research (maximum ½ page). This is not included in the 3 pages that comprise the Aims and Background/Research Plan. • Bio sketch of investigator(s). No more than 3 pages each in the most current NIH format. This is not included in the 3 pages that comprise the Aims and background/Research Plan. The bio sketch should include your support for other projects. • Budget and budget justification for funding not to exceed \$30,000 +fringe over 1 year. • Appendix (optional). The appendix is limited to 3 pages. 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.
Utilization of Core Facilities	<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 project must be completed in 1 year.</p> <p>Carry-over of funds is not allowed.</p>
Maximum Award Request	<p>\$25,000 maximum total up to \$35,000 if a CTSC Core is utilized (\$10,000 for Core utilization).</p>

	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	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: https://clinicaltrials.gov/ct2/manage-recs/fdaaa
Application	<ul style="list-style-type: none"> • 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 participations, use of animals, hazardous or radioactive materials, and recombinant DNA in their research studies. • CWRU’s CSR members will review proposals. When appropriate, external reviewers will be asked to participate in the review process • 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"> 1. Overall merit and score rating of the proposal 2. Significance, originality, and translational nature of the proposed project. 3. Feasibility and the anticipated ability of the PI and study team 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. Budget justification. 6. Partnership goals of the proposal in regard to the inter-institutional, inter-departmental and inter-generational partnerships. <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>
Resubmissions	Proposals will be reviewed and either approved or declined. All applicants receive feedback from blinded peer reviewers. Declined projects may be re-submitted to the next CSR-Themed Pilot Grant Period.

Multiple Awards	An investigator may be listed as PI or Co-investigator on any number of applications. If awarded a CSR-Themed Pilot Grant, a funded PI will be ineligible to receive another CSR-Themed Pilot grant for at least two years.
Reporting Process	Grantees are required to submit an interim report at 3 months and 6 months and a final report at the completion of the award (12 months) summarizing major activities and research findings. The CTSC CSR-Themed 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.
Change of Principal Investigator	A change of PI is not allowed. Award transfer to another institution outside of CTSC is not allowed.
Citation Policy	Citation of the CTSC award is mandatory. All pilot award recipients must acknowledge the CTSC on all relevant publications. 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.”
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 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 and electronic version of their final, peer-reviewed manuscripts upon acceptance for publication. The NIH shall implement the public access policy in a manner consistent with copyright law.

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	will be added by the CTSA administrative office in accordance with negotiated F&A rate agreement
Lab Tests - Clinical	Yes, justify and verify the costs with the laboratory
Lab Tests – Research –Core Services	Yes, justify and verify the costs with the laboratory
Malpractice Insurance	No
Membership Dues	No
Office supplies, general	No
	this is same as indirects
Parking Fees	No
Payment/Remuneration of Human Subjects	No
Patient/Participant Recruitment	No
Personnel Recruitment	No
Personnel:	
Principal Investigator/ Co-investigator Salary /Fringes	Maximum of \$5,000 (before fringe 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
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 Anita Zaremba.

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.

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 SUDEP Award 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 April 28, 2017, 11:59pm EDT**

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 Anita Zaremba, axz2@case.edu or call 216-368-1803.

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