Request for Applications
Center for SUDEP Research (CSR)
Funded by UCB

SUDEP Pilot Purpose	The Center for SUDEP Research (CSR) is an initiative that has been established to study Sudden Unexpected Death in Epilepsy (SUDEP). This Epilepsy Center Without Walls includes over 40 clinicians and scientists from 14 institutes across the U.S. and U.K. This five-year research initiative is supported by the National Institute of Neurological Disorders and Stroke at the National Institutes of Health (NIH) and brings together many of the leaders in the field of SUDEP research. The current grant RFA is generously funded by UCB.
	SUDEP is the sudden and premature death of a person with epilepsy without apparent or known cause of death. It is the most common cause of premature mortality for people with epilepsy. Individuals with refractory epilepsy have a 35% lifetime chance of succumbing to SUDEP. There are currently no targeted treatments or devices available to prevent it. The cause of SUDEP is unknown, but research efforts have centered on structural and/or functional defects in brain areas that control cardiovascular and respiratory functions. Such abnormalities can cause breathing and heart rate disruptions following a seizure, which in a subset of cases, are catastrophic and lead to sudden death.
	The CSR is composed of a multidisciplinary group of investigators with expertise in molecular biology, genetics, neuropathology, electrophysiology, brain imaging, epilepsy, respiratory physiology, cardiology, and bioinformatics. The team will be involved in nine projects that combine basic research and clinical findings with the common goal of quickly taking SUDEP lab results into the clinic.
Scope of Proposals	The CSR seeks novel pilot projects that will address the goal of understanding and eliminating SUDEP. This pilot program will award grants to national and international researchers submitting innovative proposals that compliments and expands on the SUDEP research proposed in the CSR. The CSR plans to support one clinical pilot project (clinical trials will not be funded through this mechanism, but studies involving human subjects are allowed). Successful applicants will be expected to work collaboratively with the CSR investigators.

Funding	Requests may be made for up to $75,000 in Total (Directs +Indirects) costs paid over 1 year.
Principal Investigator Credentials	This award is available to both young and established investigators exploring cutting-edge approaches to understanding and preventing human SUDEP. International applicants and applicants from outside the field of epilepsy with novel insight into the causes and prevention of SUDEP are welcome. Investigators already funded by the CSR are not eligible to apply. All materials must be submitted in English.
Number of PIs	Only one investigator can be named as PI. Additional collaborating investigators will be names as co-investigators. Co-PIs are not permitted.
New Investigators	Proposals from new investigators are strongly encouraged.
Inclusion of Co-Investigators	Applications may 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	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.
Submission –Full Application	Submit online at: http://webgrants.case.edu, due Tuesday, January 31, 2017 no later than 11:59pm EST.
Components of Application	- Complete applications will consist of: - 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 - Budget and budget justification. - Research proposal (see 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 11:59pm, Tuesday, January 31, 2017, constitutes an incomplete application. Incomplete applications will not be reviewed.
Research Proposal	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: The research proposal will include: - Specific aims (not more than 1 page) - Background and Research Plan (not more than 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. (Not more than 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. This is not included in the 3 pages that comprise the Aims and Background/Research Plan. The biosketch should include your support for other projects. (Do you currently have support for this project from other sources?). - Budget and budget justification for funding not to exceed $75,000 in direct costs +indirects over 1 year. - Other support for the proposed project (Do you currently have support for this project from other sources?)
Project Length	Proposed project must be completed in 1 year.
Maximum Award Request	$75,000 maximum total. 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	- 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. - Center for SUDEP 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: 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. The review committee would like to emphasize the importance of specifying plans for how the project will lead to funding from other federal and non-federal granting agencies.

Resubmissions	Proposals will be reviewed and either approved or disapproved. All applicants receive feedback from blinded peer reviewers.
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.
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 Center for SUDEP Research will also contact the awardees on an annual basis, 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.
Service as a Reviewer	Awardees may be included in a list of researchers to serve as potential reviewers on future Center for SUDEP NIH Research Pilot Grants.
Re-budgeting	Funds may be re-budgeted with documented justification and approval by the CSR governance. 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 is not allowed.
Citation Policy	All pilot award recipients must agree in writing to cite the award on all publications resulting from funds provided from the Center for SUDEP Research to the investigator making it possible to publish.
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.

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 January 31, 2017, 11:59pm EST.**

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. Applications that are incomplete or incorrect will be returned to the applicant for revision.