

# Centers Without Walls for Collaborative Research in the Epilepsies: Sudden Unexpected Death in Epilepsy (SUDEP)

**RFA-NS-14-004**

Pre-Applicant Webinar: November 20, 2013

Letter of intent due: February 10, 2014

Application due: March 10, 2014

RFA: <http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-14-004.html>

# Housekeeping Details

- Please mute your telephones
- If we disconnect due to technical difficulties, please remain on the line and wait until we re-connect
- There are no webinar “chat” or “raise your hand” functions : all communication will be done through email to:  
[vicky.whittemore@nih.gov](mailto:vicky.whittemore@nih.gov)
- Put “SUDEP ?” in the subject line of your email
- After the presentation, we will address questions emailed during the webinar, then, if time allows, oral questions will be taken
- The identity of persons who email questions will not be revealed to the other participants
- Slides and frequently asked questions (FAQ) will be posted on the NINDS website after the webinar

# Participants at NINDS

- Bill Benzing, Ph.D.

Scientific Review Officer

- Vicky Whittemore, PhD

Program Director, Channels Synapses and Circuits Cluster

# Purpose of RFA-NS-14-004

- Provide support for a collaborative, multidisciplinary group to accelerate the rate of progress in understanding the underlying mechanisms that contribute to sudden unexpected death in epilepsy (SUDEP), determine risk factors for SUDEP in individuals with epilepsy, and work toward intervention(s) that prevent SUDEP.

# Key Points

- The most compelling CWW applications will present a proposed strategy to identify underlying mechanisms of SUDEP, risk factors and/or ways in which to identify those at most risk for SUDEP.
- Ideally, the proposed strategy will include:
  - Multidisciplinary approaches to the study of SUDEP;
  - Investigators from multiple institutions and with varying and complimentary expertise;
  - Research at the basic and translational level and clinical studies as appropriate.

# Additional Key Points

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- The applications for a single CWW will consist of a series of linked U01 applications.
- Each U01 will be a separate component of the overall CWW.
- Each scientific project or core will be a separate U01.

# What activities are allowed in the U01?

- Basic, translational or clinical projects (not clinical trials)
- Pilot projects
- Core activities that ideally support two or more of the scientific projects
- Collaborative projects across institutions are encouraged
- Support for investigator meetings and travel between laboratories

# What must be included in the overall CWW application?

- A tightly focused, unifying theme should cross all proposed activities and components of the CWW.
- Administrative Core: One U01 application must describe the administrative and coordinating activities across all projects and cores.
- Scientific Project U01s: Should include hypothesis-driven research with specific aims.
- Scientific Core U01s: Should detail the service(s) they will provide and which projects will utilize these services.

# Other Considerations

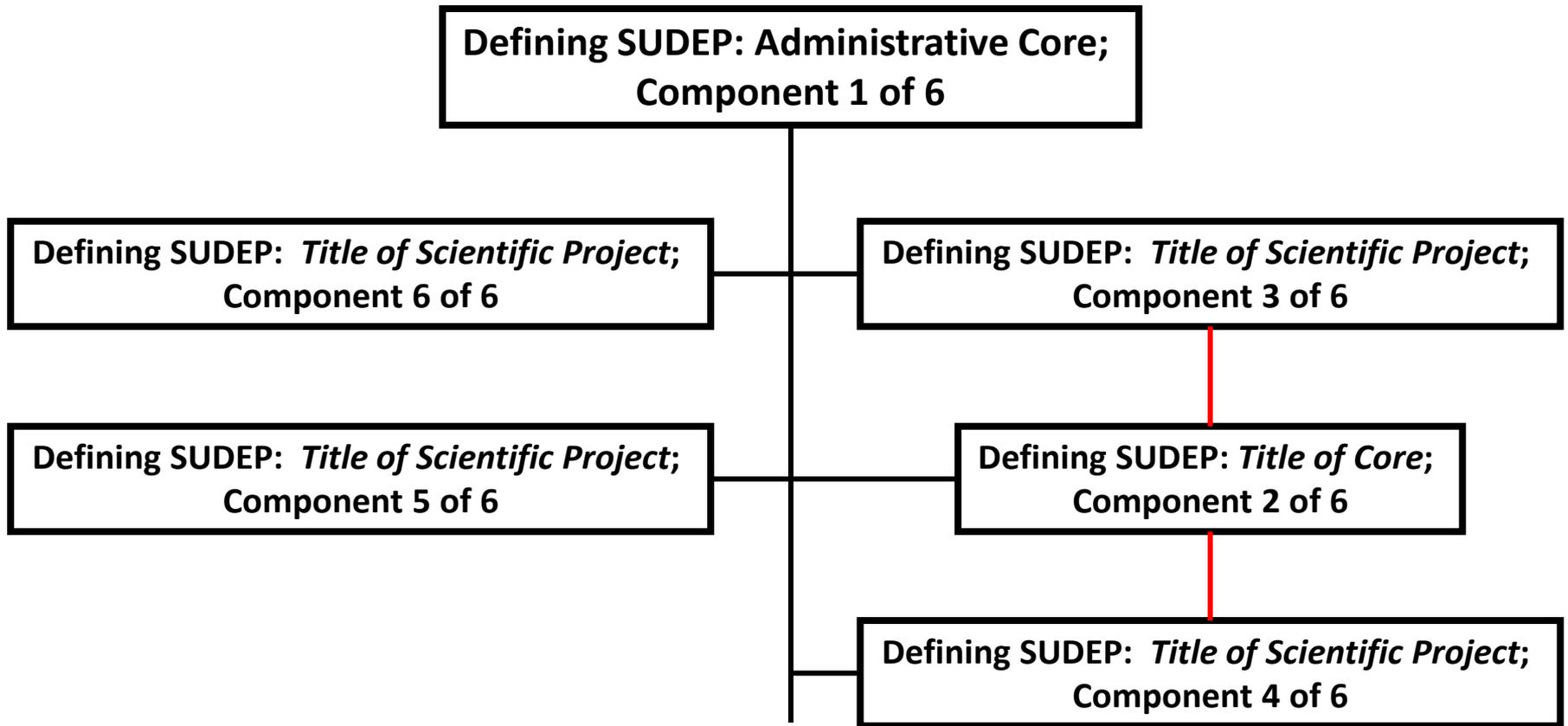
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- You may include any combination of basic, translational and clinical components (not clinical trials)
- A collaborator from outside the field of epilepsy is strongly encouraged
- Multiple PIs or single PI submission options
- Foreign institutions may apply

# What should NOT be included in the U01?

- Interventional clinical trials
  - Note: clinical trials are not permitted as a part of the Center Without Walls application.
  - Subsequent full-scale applications for interventional trials can be submitted.

# Possible Structure of Center Without Walls Application



# Budget Limit

- Budget limit is \$3,000,000 direct costs per year, for up to a total of 5 years (includes all components of the CWW).
- The budget can be divided between all the projects and core activities as needed to complete the studies.
- Budget limit calculation does not include consortium indirect costs.

# Review Criteria - General

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- Synergy: Each U01 application will be reviewed for the contribution the scientific project or core makes to the overall composition of the Center Without Walls, as well as the synergy between the scientific projects and core(s).
- Rigor and Transparency: Each U01 application will be evaluated for the scientific rationale/premise of the study and the study design.

# Review Considerations - Significance

- Are the proposed projects focused on an aspect of SUDEP in which there is potential to make significant progress quickly?
- If successful, do the projects establish a “proof-of-concept” experimental framework that could be generalized to organize subsequent translational research efforts for intervention(s) that would reduce the number of cases of SUDEP?
- Will the results of the studies lead to changes in clinical care for those individuals with epilepsy and for those at risk for SUDEP?
- How significant would the reduction in disease burden be if the research efforts are successful?

# Review Considerations – Investigator(s)

- Is the collaborative team comprised of investigators who are among the most appropriate participants for this project?
- Does the investigative team include at least one individual with expertise from outside the field of epilepsy?
- Is there synergy between the investigators that creates a unique research opportunity for discovery science in SUDEP?

# Review Considerations - Innovation

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- Standard criteria

# Review Considerations - Approach

- Are the methods/techniques appropriate for the proposed hypotheses?
- Are there components that involve the use of animal models to explore specific aspects of SUDEP?
- Are there components that involve studying human subjects and/or risk factors in individuals with epilepsy?
- Will the proposed experiments result in rigorous findings that can be utilized in future studies (either translational or clinical studies)?

# Expectations for Pre-clinical Studies

- There is increasing awareness among neurological disease communities that to assess the predictive value of preclinical research, sufficient information must be available about study design, execution, analysis, and interpretation.
- NINDS urges applicants to the program to consider these elements when describing supporting data and designing the proposed studies.
- [http://www.ninds.nih.gov/funding/transparency\\_in\\_reporting\\_guidance.pdf](http://www.ninds.nih.gov/funding/transparency_in_reporting_guidance.pdf)

# Review Considerations - Environment

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- Standard criteria

# Review Criteria for Administrative Core

- Is there a clear, detailed leadership plan for managing the Center Without Wall's research and administration, ensuring appropriate prioritization of research, needed course corrections and problem identification and resolution, and effective sharing of resources, that conveys a high likelihood of effective, productive management of the Center Without Walls as a whole?
- Are the core personnel qualified and experienced in the administration of a large, multi-component research program?
- Are there an organizational structure and charter that will facilitate coordination, integration and timely evaluation of activities and progress? Does the organizational plan include guidelines for authorship on all publications resulting from research supported by the U01 grants, and a discussion of the use of the NINDS Common Data Elements for all proposed clinical studies as appropriate?
- Is there discussion for the utilization, as appropriate, of current NINDS-funded resources such as the NINDS Biospecimen Repository at Coriell, other Epilepsy Center Without Wall initiatives, and the International Epilepsy Electrophysiology Portal (IEEG), etc.?
- Are there a plan and a budget to support pilot and collaborative projects if included in the application and is the plan adequate and appropriate?
- Is there a plan to support and encourage collaborative projects between the funded U01 scientific projects and cores for trainees and young investigators to engage in projects that involve two or more of the scientific projects or cores?

# Review Criteria for Scientific Core(s)

- Each Core will be assessed based on the following criteria:
  - Is the proposed Core well matched to the needs of the overall program? Does it provide essential facilities or services for two or more research projects?
  - What is the overall quality of the proposed core services? Are there adequate quality control processes proposed for the facilities or services provided by the Core (including procedures, techniques, and quality control)? What are the criteria for prioritization and usage of Core products and/or services?
  - Are the qualifications, experience, and commitment of the leader(s) of the Core and other key personnel adequate and appropriate for providing the proposed facilities or services?
  - Will the proposed Core provide cost effective services to the Program?
  - Is the environment for the Core adequate to support the program as proposed?

# Timeline

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- February 10, 2014: Letters of Intent due
- March 10, 2014: Applications due
- June/July 2014: Scientific review
- September 2014: Advisory Council review
- September/October 2014: Earliest start date

# Additional Questions?

- <http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-14-004.html>
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