Sleep Research Society Foundation

Focused Research AWARD

2023 Request For Applications

Focused Research Award on Cardiovascular Outcomes in Narcolepsy

Submission Deadline: Tuesday, January 31, 2023, at 11:59pm CT

SUBMIT ONE PDF FILE WITH ALL CONTENT TO: foundation@srsnet.org

Overview

The goal of this focused research grant is to improve our understanding of cardiovascular outcomes in patients with Narcolepsy. This grant mechanism is a competitive grant award, which will be given to a successful candidate with the most meritorious application. It is open to promising early career researchers as well as established researchers. Expertise with analyzing large claims-based data and electronic medical records (EMR), and/or big-data analytics is a pre-requisite for the successful applicant or member(s) of the investigative team. One award will be funded up to $400,000 for a 1-year period with tight timelines for performance and deliverables. The ability to ***rapidly*** execute data use agreements with third-party data sources that provide claims-based data (specifically, IBM-Truven Health Analytics Data sets [Merative™ MarketScan®] or Optum Claims Data) and produce deliverables (research presentations and peer-reviewed publications) will be a critical evaluation criterion. Recipients must be willing to work with the SRSF honest broker for data-analytical methods and approaches as needed during the funding period.

Scope of Research Supported

The award is intended to further our understanding of cardiovascular outcomes in patients with Narcolepsy by performing rapid analyses of readily available large datasets.

Only one award will be chosen under this targeted funding mechanism.

The Sleep Research Society views diversity, equity, and inclusion as vital components of its mission to advance sleep and circadian science. We especially encourage applications from those underrepresented in science including those based on age, race, ethnicity, sex, gender identity and expression, sexual orientation, disabilities, socioeconomic status and disadvantaged backgrounds, religious beliefs, political affiliations, life and research experiences, background and perspectives, national origin, military or veteran status, geographic regions, and cultures.

Requirements for Applicants

- Principal investigator (PI) must have a Doctoral level degree, such as MD, PhD, DO and/or comparable degree.
- Applicants may be from any career stage. Early career or established investigators with a doctoral degree who are at any level with expertise in extracting and analyzing large

claims-based datasets, EMR-based data, big-data, or similar fields are strongly encouraged to apply. If the PI does not have the aforementioned expertise, they should at least have clinical research expertise in Narcolepsy (or another sleep disorder) and must partner with investigators with expertise in big-data analytics. This mechanism will allow for multiple PI (MPI) approaches, but the MPIs need to demonstrate a prior history of successful collaboration and complementary expertise.

- This funding mechanism is not suited for a mentored award as the funding may not be used towards career development. Funds obtained from this grant mechanism are to be used to study the relationship between Narcolepsy and cardiovascular disease.
- Complete Application, including all components noted on the Application form.
- SRS membership in good standing.

Description of funding opportunity

(a) Background: Narcolepsy is a sleep disorder that is defined by a distinct set of clinical symptoms, neurophysiological findings, and low hypocretin levels. Hypocretin deficiency has been clearly implicated in the pathobiological process of Narcolepsy but hypocretin is also known to regulate cardiovascular physiology. Specifically, hypocretin deficiency may cause autonomic dysfunction and in some small studies it has been reported that narcolepsy may be independently associated with multiple cardiovascular risk factors, comorbidities, and cardiovascular disease. Short-term physiological studies show non-dipping blood pressure in patients with Narcolepsy in association with Rapid Eye Movement (REM sleep) dysregulation. Non-dipping blood pressure, in turn, has been independently associated with an increased risk for cardiovascular events and even mortality in epidemiological studies. Moreover, hypertension is also prevalent in patients with narcolepsy and the disrupted nighttime sleep and excessive daytime sleepiness, which are clinical features of narcolepsy, have also been associated with increased cardiovascular morbidity. Moreover, co-morbid disease conditions (e.g., obesity) and narcolepsy medications (i.e., stimulants) may confer additional risk to the cardiovascular health. An improved understanding of the cross-sectional associations and longitudinal relationship with cardiovascular patient outcomes is direly needed. Prospective studies with measurements and longitudinal follow-up could be considered as an ideal approach, but rapid analyses of readily available datasets derived from administrative claims data and supplemented by EMR data may accelerate discoveries and generate new hypotheses, which, in turn, can be tested in future prospective studies. Local registries are less likely to be nationally representative with regards to geography, race/ethnicity, and socioeconomic status.

(b) Objective: To further our understanding of cardiovascular outcomes in patients with narcolepsy by performing rigorous and rapid analyses of readily available large datasets. Additional objectives that are responsive and/or related to this overarching objective are encouraged.

(c) Application type: Data science approaches to health discovery and innovation. Clinical trials, prospective observational studies, and preclinical studies will be considered nonresponsive and such applications will be administratively triaged.

(d) Number of awards: One.

(e) Award budget: $400,000. It is anticipated that purchasing access to the datasets (specifically, IBM-Truven Health Analytics Data sets [Merative™ MarketScan®] or Optum Claims Data) may cost $100,000 to $150,000 for single purpose use. A successful

application is expected to have salaries to cover sufficient effort for a senior statistician and database manager/coder in addition to the investigative team. Travel costs are allowed but need to be reasonable (< $5,000 total). Costs for the SRSF honest broker need ***not*** be included. Access to high performance computing laboratories in the absence of such facilities in the applicant's institution is an allowable cost.

(f) Page limits: 7-page limit that is applied towards specific aims (1-page), significance, innovation, preliminary data, and approach including the statistical plan. The 7-page limit does not apply to the following required elements: Biosketches for key personnel (5-page NIH format), budget, budget justification, facilities and resources, inclusion of women, children, and targeted enrollment tables (NIH or similar), and abstract (250 words). Formatting requirements are as follows: A minimum of 0.5 inch margins, 11-point Arial or similarly sized sans serif font, and line spacing of 1.

(g) Indirect costs: Indirect costs are disallowed as per the policy of the Sleep Research Society Foundation. Fringe rates can be applied as per institutional policies and rates.

(h) Award period: One year

(i) Key dates:
   a. Application Due: Tuesday, January 31, 2023, at 11:59 PM Central Time
   b. Peer review: February/March 2023
   c. Award decision and issuance of draft contract: April/May 2023
   d. Anticipated start date: July 1, 2023
   e. Anticipated date when the final report is due: June 30, 2024

(j) Review Process: Applications will be reviewed by a special review panel through the SRS Scientific Review Committee (SRC). Final funding decisions will be made solely by the SRSF based on the SRC's review of the applications.

(k) Timelines and deliverables:
No cost extensions will only be considered in extreme circumstances (i.e., natural disasters).
   a. 0 days: Approval or exempt status determination by Institutional Review Board must be obtained during the Just-in-Time period (April 2023-June 2023). Earlier start date is feasible. 50% of award will be issued to successful applicant upon execution of the contract.
   b. 60 days: Evidence of successful execution of Data Use Agreement with 3rd party or attestation that investigators are in possession of datasets obtained previously.
   c. 90 days: Attestation of successfully extracting and cleaning dataset with all required variables for analyses.
   d. 120 days: Attestation of ongoing discussions with SRSF honest broker for data-analytical approaches (if needed). Applicant team will receive formal introduction to SRSF honest broker upon award notice in April/May 2023.
   e. 180 days: Interim progress report update to SRSF regarding progress related to data extraction, data analysis, project timelines, and deliverables. 25% of the total award will be distributed upon satisfactory interim progress report.
   f. 240 days: Evidence of submission of a manuscript to a peer-reviewed journal.
   g. 365 days: Final report with status of scientific publications and presentations. The final 25% of the award will be distributed upon acceptance of the final report.

(l) Funding source: This funding mechanism was made feasible by a donation from Jazz Pharmaceuticals, Inc. Jazz Pharmaceuticals will not participate in or influence the review process.

Evaluation criteria

- Prior track-record of publications from PI, MPI, or co-investigators of patient outcomes derived from claims-based data.
- Various aspects of the proposal ranging from significance, innovation, scientific rigor, feasibility, environment, and data analytical plan. Additional criteria include the data-security plan, and prior track record of impactful publications.
- Demonstrable ability to rapidly execute data use agreements with third-party data sources that provide nationally representative claims-based datasets (specifically, specifically, IBM-Truven Health Analytics Data sets [Merative™ MarketScan®] or Optum Claims Data).
- Capability or willingness to work with the SRSF Honest Broker designated by the Sleep Research Society Foundation for data analytical methods and approaches as needed during the funding period.
- Clearly articulated project plan and evident capacity to accomplish the rapid timelines and deliverables.
- Data security and other steps taken to prevent data loss, data breach, and loss of data integrity is another evaluation criterion.
- Applicants from the University of Arizona are ineligible to apply due to a conflict of interest with the SRSF Honest Broker, Sairam Parthasarathy, MD. All applicants with a conflict of interest with the SRSF Honest Broker are ineligible. The following constitutes a conflict of interest:
    - Applicant is employed or contracted by the University of Arizona.
    - Applicant is a current collaborator with or within the past three years has published with, collaborated with or has been in a mentoring relationship with the SRSF Honest Broker.

Please contact the SRSF at foundation@srsnet.org or (630) 737-9702 with any questions.