



## 2022 Strategic Research Grant: Treatment of Central Disorders of Hypersomnolence

<b>ISSUE DATE:</b>	September 13, 2021
<b>LETTER OF INTENT DUE DATE:</b>	October 11, 2021 by 11:59 pm ET
<b>INVITATIONS TO SUBMIT FULL APPLICATION:</b>	By January 28, 2022
<b>APPLICATION DUE DATE:</b>	July 29, 2022 by 11:59 pm ET
<b>GRANT SELECTION NOTIFICATION</b>	By July 29, 2022
<b>PERIOD OF PERFORMANCE:</b>	Category I: 1-3 years Category II: 1-2 years Category III: Up to 1 year
<b>AMOUNT OF GRANT:</b>	Category I: Up to \$250,000 Category II: Up to \$100,000 Category III: Up to \$50,000
<b>LINK TO LETTER OF INTENT:</b>	<a href="https://www.GrantRequest.com/SID_5880?SA=SNA&amp;FID=35089">https://www.GrantRequest.com/SID_5880?SA=SNA&amp;FID=35089</a>
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The AASM Foundation is committed to improving patient-centered diagnosis and care for all patients with sleep disorders. To ensure that there is a continued advancement in effective diagnosis and care of patients with sleep disorders, the AASM Foundation provides research funding through the Strategic Research Grant. This grant is investigator-initiated and supports high-impact research projects aimed at addressing gaps in knowledge that impact the ability to provide optimal, patient-centered, cost-effective diagnosis and care for patients with sleep disorders.

This is a focused request for applications (RFA) open to projects which address research gaps in the treatment of central disorders of hypersomnolence that were identified in the recently published systematic review titled, [\*Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment\*](#). Details for each research domain and related topic areas of interest are provided below. Only applications that fit into one or more of these research domains and topic areas will be considered.

## **1. Comparisons between Treatments for Central Disorders of Hypersomnolence**

There is a need for studies that directly compare different medications used to treat central disorders of hypersomnolence. Research topics that fall under this research domain include:

- a. Comparative-effectiveness studies of new medications that enter the market against standard treatments so physicians and patients can factor this information into treatment decisions. This includes studying treatment options other than stimulants for idiopathic hypersomnia, since some patients cannot tolerate stimulants.
- b. Well-designed studies evaluating commonly used traditional stimulants for central disorders of hypersomnolence and selective serotonin reuptake inhibitors/serotonin and norepinephrine reuptake inhibitors cataplexy treatments for patients with narcolepsy type 1.
- c. Prospective clinical trials for venlafaxine, a drug widely used for treating cataplexy. The low cost of this therapy is attractive, and it is already commonly used across the world.

## **2. Patient-centered Outcome Measures for Central Disorders of Hypersomnolence**

There is a need to identify, develop and validate patient-centered outcome measures that can be used to evaluate and monitor important outcomes in patients with central disorders of hypersomnolence. Research topics that fall under this research domain include:

- a. Identify validated outcome measures that most closely reflect patient priorities in order to develop and validate disease-specific patient-reported outcome measurement tools, and to delineate clinical significance thresholds to harmonize future research and facilitate future clinical guideline development.
- b. Research focused on quality of life measures, both cross-sectional and longitudinal, to help the field better understand aspects of the disease most disruptive to patient lifestyles.

### **3. Mechanistic Studies for Understanding Central Disorders of Hypersomnolence**

Studies designed to understand the biological process and pathophysiology of central disorders of hypersomnolence and the mechanism of action of certain treatments are needed. Research topics that fall under this research domain include:

- a. Research to understand the mechanisms of hypersomnia and excessive daytime sleepiness in specific conditions, so that more targeted therapies can be developed.
- b. Understanding the role of the innate and adaptive immune system in the development of narcolepsy should herald clinical trials in immune modulating treatments that could attenuate disease severity.
- c. Understanding the molecular architecture of the human orexin receptor<sub>1/2</sub> to inform development and testing of orexin specific therapies.
- d. Mechanistic data for understudied conditions like Kleine-Levin syndrome, idiopathic hypersomnia, narcolepsy type 2 and hypersomnia due to specific medical and psychiatric disorders for targeted drug development and testing.

### **4. Central Disorders of Hypersomnolence in Pediatric Populations**

Many central disorders of hypersomnolence start in childhood and adolescence, yet clinical trials of medications are lacking for those under 18 years of age. Research topics that fall under this research domain include:

- a. High quality randomized control trials for pediatric patients with central nervous system hypersomnia since children and adolescents may react differently to medications for hypersomnolence than adults, and side effect profiles can vary based on patient age.

### **5. Behavioral and Psychological Treatments for Central Disorders of Hypersomnolence**

Reliance on medications alone to treat central disorders of hypersomnolence is likely insufficient without broader guidance on behavioral and environmental influences on symptom management. Research topics that fall under this research domain include:

- a. Evaluating cognitive behavior therapy (in-person, online), sleep scheduling, naps, exercise, and specific diets for furthering medication effects and/or demonstrating independent treatment benefit.

**Note:** *Proposals are encouraged to use standardized, validated assessments, which will permit clinicians and patients to compare clinical trial data to get an estimate of comparative effectiveness.*

## **FUNDING INFORMATION**

The Strategic Research Grant program is organized into three categories to allow flexibility and a range of funding opportunities to potential applicants:

- Category I is for those applicants seeking funding for projects up to \$250,000 and covers a project period of up to three years.
- Category II is for those applicants seeking funding for projects up to \$100,000 and covers a project period of up to two years.
- Category III is for those applicants seeking funding for projects up to \$50,000 and covers a project period of up to one year.

The funds can be used for research expenses such as salary support (commensurate with current stipends or salaries), supplies, participant costs and institutional overhead. There are no restrictions on the distribution of expenses, however, indirect costs are capped at 8%. The grant is executed as a contract between the AASM Foundation and the grantee's institution.

## **ELIGIBILITY**

The following individuals are eligible to apply:

- Individuals with the following education and training are eligible to apply:
  - Master's level degree or higher.
- Individuals may apply for multiple AASM Foundation grants, however, the same proposal (i.e., projects with budgetary and scientific overlap) may not be submitted for multiple requests for applications in a given cycle.
- Individuals who are the Principal Investigator on an open or previous AASM Foundation research grant at the time of the application deadline are eligible to apply if they can demonstrate that there is no budgetary or scientific overlap between their open grant and the new project they are applying for funding. If there is

budgetary and/or scientific overlap between projects, the applicant must indicate their plan to close their open grant in the event their new application is selected for funding (e.g., relinquish the current grant or complete the current grant to start the new grant).

- International individuals who meet all the eligibility criteria are eligible to apply; however, payment of grant funds must be accepted by the institution in US dollars.

## INELIGIBILITY

The following individuals are not eligible to apply:

- Individuals who have a financial conflict of interest or have the potential to incur significant financial benefit from the proposed work and beyond the work itself are not eligible to apply.
- Individuals who are seeking funding from AASM Foundation research grants to support ongoing projects that are currently funded by another granting body or supplement ongoing work (e.g., enrolling additional subjects into an ongoing trial) are not eligible to apply.

**Note:** *The principal investigator will be required to make a statement to this effect prior to execution of the contract.*

## LETTER OF INTENT REQUIREMENT

This grant is a two-stage application process, in which a letter of intent (LOI) is required prior to submission of a full application. Applicants will then be notified whether they will be invited to submit a full application. If the LOI is not approved, the applicant may not apply for the grant.

Please note that the information submitted in the LOI (e.g., grant category, key personnel, research domain) is final and those invited to submit a full application will be bound by the content of their approved LOI unless a modification was specifically requested or approved by the AASM Foundation.

For an overview on how to write an effective LOI and Application for the AASM Foundation Strategic Research Grant, please view the following resources:

[Strategic Research Grant Letter of Intent Guide](#)

[Strategic Research Grant: How to Submit a Competitive Letter of Intent and Application Webinar](#)

## LOI REVIEW CRITERIA

For applicants who voluntarily submit a LOI, the AASM Foundation Executive Committee will review all submitted LOIs. The following criteria will be considered in determining whether the applicant will be invited to submit a full application for consideration:

- 1. Responsiveness:** Responsiveness to the one of the topic areas being requested as part of this RFA.
- 2. Significance and Innovation:** Potential impact/significance and innovation of the planned research in advancing the field sleep medicine.
- 3. Feasibility:** Feasibility in carrying out the planned research.
- 4. Methodology:** Overall quality of the methods and analytic plan.
- 5. Investigators:** Expertise and experience of the investigators and other key personnel conducting the planned research.
- 6. Inclusivity:** Inclusion of individuals of all ages, including children, adolescents and older adults, unless there are scientific or ethical reasons not to include them.

#### **APPLICATION GRANT REVIEW CRITERIA AND PROCESS**

Once LOIs are reviewed, invitations will be sent out to applicants who have a favorably reviewed LOI so a full application may be submitted. For invited applicants who submit a full application, a grant review committee, appointed by the AASM Foundation Executive Committee, will evaluate and score all submitted applications. Factors that will be taken into consideration include:

- 1. Significance:** Strong scientific premise of planned research in addressing important problems or critical barriers needed to progress the sleep medicine field.
- 2. Investigators:** Experience, training, and ongoing record of accomplishments of the principal investigator(s) and key personnel.
- 3. Innovation:** Use of novel theoretical concepts, approaches or methodologies, instrumentation, or interventions that challenge and seek to shift current research or clinical practice paradigms.
- 4. Approach:** Strategies to ensure a robust and unbiased approach, methodology, analyses, and benchmarks for success are well-reasoned and appropriate for the specific aims of the planned research.
- 5. Environment:** Institutional support, availability of equipment and other physical resources that contribute to the probability of success of the planned research.

Only materials submitted within the application will be used in the evaluation of applications. The AASM Foundation Executive Committee will submit funding recommendation to the AASM Foundation Board of Directors based on the Grant

Review Committee scores. The AASM Foundation Board of Directors will make the final funding decisions.

## PAYMENT SCHEDULE

Category I Grants	
<b>Payment #1</b> – Upon execution of contract	50%
<b>Payment #2</b> – At project midpoint after approval of Progress Report	40%
<b>Payment #3</b> – Upon receipt and approval of Final Report	10%

Category II and Category III Grants	
<b>Payment #1</b> – Upon execution of contract	90%
<b>Payment #2</b> – Upon receipt and approval of Final Report	10%

If unique circumstances are explained in the budget justification of the applicant’s proposal, the Board of Directors will consider requests for an alternate payment schedule, with a maximum variance of 10%.

***Note:** Once a contract is executed for the grant, reallocation of funds of <10% do not require approval.*

## DELIVERABLES AND EXPECTED OUTCOMES

The AASM Foundation Strategic Research Grant supports high-impact research which will advance the diagnosis, treatment, and delivery of patient-centered care across the healthcare continuum for patients with sleep disorders. The AASM Foundation intends that the research funded by this grant will lead to the publication of original research in peer-reviewed journals.

Applicants are expected to address the specific aims as described in the application. Major modification of the proposed aims requires AASM Foundation Board of Directors or Executive Committee approval.

The expected results and deliverables should be clearly stated in the application. The applicant must submit progress and final reports during the project period, describing project activities and results, as outlined below. Failure to meet the deliverables or submit progress or final reports may result in termination of project funding.

## REPORTING SCHEDULE

<b>Progress Reports</b>	Every six months
<b>Final Report</b>	Within 90 days of grant completion

Outcomes evaluation is an essential component of this grant. All proposals must identify the goals and appropriate outcomes measures of the research. The outcomes should align with the goals and objectives stated in the applicant’s proposal for this grant.

**HUMAN/ANIMAL SUBJECT PROTECTION PLAN**

If using human or animal subjects, the applicant will be responsible for obtaining Institutional Review Board (IRB) or Institutional Animal Care and use Committee (IACUC) approval. The IRB or IACUC letter of approval for the specified project must be on file with the AASM Foundation office prior to the execution of the contract. No funds will be released for the project without receipt of written approval by an IRB or IACUC. Failure to obtain IRB or IACUC approval will result in retraction of the grant.

**LOI AND APPLICATION**

***Step 1: AASM Foundation Grant Request registration***

To apply for this grant, you must register on [AASM Foundation Grant Request](#). Please refer to the [AASM Foundation Grant Request User Access Guide](#) for guidance on setting-up an account.

***Step 2: Complete LOI Submission***

**[ACCESS THE 2022 STRATEGIC RESEARCH GRANT: TREATMENT OF CENTRAL DISORDERS OF HYPERSONNOLENCE LETTER OF INTENT](#)**

The LOI Checklist below shows required attachments to be uploaded.

**LOI CHECKLIST**

Form	Page/Word Limit
<input type="checkbox"/> <b>Face page</b> A. Principal investigator B. Sponsoring organization C. Project information and alignment with RFA	C. 300 words, max
<input type="checkbox"/> <b>Project Personnel</b> A. Principal Investigator biosketch and other support page B. Key Personnel: Biosketch and other support	Biosketch: 5 pages per individual Other support page: No page limit

<input type="checkbox"/> <b>Letter of Intent</b>	3 pages, excluding references
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### ***Step 3: Complete Application (invited applicants only)***

For invited applicants, full applications must be completed and submitted through [AASM Foundation Grant Request](#). A special link for submitting the full application will be sent to invited applicants. Instructions for required forms are available via the online submission system. The Application Checklist below shows required attachments to be uploaded.

#### **APPLICATION CHECKLIST (INVITED APPLICANTS ONLY)**

<b>Form</b>	<b>Page/Word Limit</b>
<input type="checkbox"/> <b>Face Page</b> A. Sponsoring organization page <i>Note: The principal investigator, sponsoring organization, and project information will be pre-populated in the face page form. Any changes require prior approval from the AASM Foundation.</i>	
<input type="checkbox"/> <b>Research Plan and Goals</b> A. Abstract B. Research plan and goals	A. 200 words, max B. 6 pages, excluding citations
<input type="checkbox"/> <b>Project Personnel</b> <i>Note: The principal investigator and key personnel biosketches and other support pages will be pre-populated in the project personnel form. Any changes require prior approval from the AASM Foundation.</i>	
<input type="checkbox"/> <b>Letters of Support</b>	1 page each
<input type="checkbox"/> <b>Budget and Budget Justification</b> A. Budget B. Budget justification	B. 2 pages
<input type="checkbox"/> <b>Human Subjects/Animal Research Protection Plan</b>	3 pages

### **GRANT QUESTIONS**

We encourage potential applicants to contact us early in the application process with questions. Eligibility questions may need to be reviewed by a member of the AASM Foundation Executive Committee, so please allow for at least a 1-week response time for eligibility questions. For all other inquiries, please allow a minimum of two business days for a response. Please note that questions received within 48 hours of an application deadline may not be answered before the deadline.

