

2022 Strategic Research Grant: Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea

ISSUE DATE:	September 13, 2021
LETTER OF INTENT DUE DATE:	October 11, 2021 by 11:59 pm ET
INVITATIONS TO SUBMIT FULL APPLICATION:	By January 28, 2022
APPLICATION DUE DATE:	March 14, 2022 by 11:59 pm ET
GRANT SELECTION NOTIFICATION	By July 29, 2022
PERIOD OF PERFORMANCE:	Category I: 1-3 years Category II: 1-2 years Category III: Up to 1 year
AMOUNT OF GRANT:	Category I: Up to \$250,000 Category II: Up to \$100,000 Category III: Up to \$50,000
LINK TO LETTER OF INTENT:	https://www.GrantRequest.com/SID_5880?SA=SNA&FID=35091
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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 use of continuous positive airway pressure (CPAP) treatment for obstructive sleep apnea (OSA). This a timely RFA in response to the <u>Agency for Healthcare Research and Quality Draft Technology Assessment – Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea and future research recommendations included in the <u>multi-society comment letter</u>. Details for each research domain and related topic areas of interest are provided below. Only applications that fit into one of these research domains and topic areas will be considered.</u>

1. Alternate Study Designs and Analytical Strategies for Assessing CPAP Treatment for OSA

There is a need for studies that use alternate designs and analytical strategies for determining if treatment of OSA with CPAP improves clinically important outcomes. Research topics that fall under this research domain include:

- a. Alternate randomized control trials, such as adaptive enrichment designs, sequential, multiple, assignments, randomized trials, blinded randomization trials with sham, etc.
- b. Adaptive trials and studies of CPAP withdrawal.
- c. Alternative non-randomized study designs, including carefully designed propensity score matching studies.

2. Studies that Enhance Prediction of Outcomes

It is acknowledged that current physiological measures of OSA, such as AHI, are limited and there is a need for novel measures that enhance prediction of outcomes. Research topics that fall under this research domain include studies that use:

- a. Molecular biomarkers and omics strategies to predict outcomes.
- b. Genetic markers to predict outcomes.
- c. Novel physiologic measures to predict outcomes.

3. Special OSA Patient Populations

There is considerable heterogeneity in patients with OSA both from a clinical symptomatic perspective that affect outcomes and individual variation in outcomes. Research topics that fall under this research domain include studies in patients with:

- a. Depression or anxiety
- b. Cognitive impairment
- c. Specific cardiovascular disorders

4. Enhancing Long-Term CPAP Adherence

There is need for establishing successful interventions and methods that optimize long-term CPAP adherence in patients with OSA in studies. Research topics that fall under this research domain include:

- a. Education at initiation of CPAP therapy
- b. Behavioral interventions
- c. Troubleshooting methods
- d. Remote monitoring
- e. Use of telehealth

Note: Proposals are encouraged to recruit and study patients who will likely benefit from CPAP for a specific outcome.

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:
 - o 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

<u>Strategic Research Grant: How to Submit a Competitive Letter of Intent and Application Webinar</u>

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		
Payment #1 – Upon execution of contract	50%	
Payment #2 – At project midpoint after approval of Progress Report	40%	
Payment #3 – Upon receipt and approval of Final Report	10%	

Category II and Category III Grants		
Payment #1 – Upon execution of contract	90%	
Payment #2 – 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

Progress Reports	Every six months
Final Report	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 <u>AASM Foundation Grant Request</u>. Please refer to the <u>AASM Foundation Grant Request User Access Guide</u> for guidance on setting-up an account.

Step 2: Complete LOI Submission

ACCESS THE 2022 STRATEGIC RESEARCH GRANT: CONTINUOUS POSITIVE
AIRWAY PRESSURE TREATMENT FOR OBSTRUCTIVE SLEEP APNEA LETTER OF
INTENT

The LOI Checklist below shows required attachments to be uploaded.

LOI CHECKLIST

Form	Page/Word Limit
☐ Face page	
A. Principal investigatorB. Sponsoring organizationC. Project information and responsiveness to RFA	C. 300 words, max
 □ Project Personnel A. Principal investigator biosketch and other support page B. Key personnel biosketch and other support page 	Biosketch: 5 pages per individual Other support page: No page limit
☐ Letter of Intent	3 pages, excluding references

Step 3: Complete Application (invited applicants only)

For invited applicants, full applications must be completed and submitted through <u>AASM Foundation Grant Request</u>. 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)

Form	Page/Word Limit	
☐ Face Page		
A. Sponsoring organization page Note: The principal investigator, sponsoring organization, and project information will be prepopulated in the face page form. Any changes require prior approval from the AASM Foundation.		
☐ Research Plan and Goals	A. 200 words, max	
A. Abstract	B. 6 pages,	
B. Research plan and goals	excluding citations	
Project Personnel		
Note: The principal investigator and key personnel biosketches and other support pages will be prepopulated in the project personnel form. Any changes require prior approval from the AASM Foundation.		
☐ Letters of Support	1 page each	
☐ Budget and Budget Justification	B. 2 pages	

A. Budget	
B. Budget justification	
☐ Human Subjects/Animal Research Protection Plan	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.