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| This document is provided to potential applicants for informational purposes only and should not be submitted as an application for the 2023 Strategic Research Grant: Hypopnea Scoring Criteria. Applications will only be accepted through the [AASM Foundation Grant Request](https://www.GrantRequest.com/SID_5880) online portal. Please refer to the [AASM Foundation Grant Request User Access Guide](https://foundation.aasm.org/wp-content/uploads/sites/2/2018/03/AASM-Foundation-Grant-Request-Account-Access-Guide.pdf) for guidance on setting up an account. |

**About This Grant**

Congratulations on being invited to submit your full application for the 2023 Strategic Research Grant. Please note that the information submitted in the approved letter of intent (LOI) (e.g., category, key personnel, 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 and approved by the AASM Foundation. If you plan on submitting a modification, please submit your request no later than March 3, 2023.

This AASM Foundation research grant is supported by the American Academy of Sleep Medicine.

This is a focused request for applications (RFA) open to projects that will **retrospectively** analyze data to evaluate the impact of diagnosis and treatment of obstructive sleep apnea (OSA) based on the hypopnea scoring criteria utilized in adult patients. Currently, the AASM Scoring Manual includes two rules for scoring hypopneas in adults:

***Recommended Rule***

Score a respiratory event as a hypopnea if ALL of the following criteria are met:

#### a. The peak signal excursions drop by ≥30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an *alternative* hypopnea sensor (diagnostic study).

#### b. The duration of the ≥30% drop in signal excursion is ≥10 seconds.

#### c. There is a ≥3% oxygen desaturation from pre-event baseline or the event is associated with an arousal.

***Acceptable Rule\****

Score a respiratory event as a hypopnea if ALL of the following criteria are met:

#### a. The peak signal excursions drop by ≥30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an *alternative* hypopnea sensor (diagnostic study).

#### b. The duration of the ≥30% drop in signal excursion is ≥10 seconds.

#### c. There is a ≥4% oxygen desaturation from pre-event baseline.

\*Currently, the rule required in Medicare coverage determinations.

Using different criteria for scoring hypopnea can change the determinations made about diagnosis when assessing patients suspected to have OSA. In 2018, the AASM published a position statement, titled [*Polysomnography for Obstructive Sleep Apnea Should Include Arousal-Based Scoring*](https://jcsm.aasm.org/doi/pdf/10.5664/jcsm.7234)*,* which asserts the importance of recognizing respiratory events leading to arousal. Accounting for both oxygen desaturations and arousals, can help more definitively rule out the presence of OSA in patients with symptoms of excessive daytime sleepiness, fatigue, insomnia, or other neurocognitive symptoms. Not accounting for arousal-based scoring may lead to a lack of proper diagnosis of OSA, misclassification of OSA severity, or misidentification of another sleep disorder or medical disorder.

The AASM Hypopnea Scoring Rule Task Force held a series of meetings to help identify gaps in research that would strengthen the evidence base for how outcomes are impacted when utilizing the AASM *Recommended* hypopnea scoring criteria in adults compared to other hypopnea scoring criteria. It was determined that assessing the benefit of treatment in patients diagnosed with OSA based on the *Recommended* hypopnea scoring rule, but not diagnosed using the *Acceptable* hypopnea scoring rule, is important.

There are several data sets available from previous large OSA studies performed, patient registries, and large health systems that have potential to be reanalyzed to provide additional information. This request for applications is specifically for projects that will perform retrospective analysis of existing data sets to assess the impact of treatment in patients with OSA who qualify for treatment using the *Recommended* hypopnea scoring criteria but not the *Acceptable* scoring criteria. Analyses of interest in this OSA population include:

* + Studies that assess differences in outcomes of interest, including sleepiness, quality of life, daytime function, excess mortality as well as neurocognitive, metabolic, and/or cardiovascular outcomes.
	+ Studies that assess and compare outcomes in subpopulations of patients (e.g., sex, age, race/ethnicity).
	+ Studies that evaluate the association between untreated OSA and comorbidities (e.g., depression, hypertension).

**This application is due no later than March 13, 2023 by 11:59 pm Eastern time.**

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 the application deadline may not be answered before the deadline.

*Please note this application CANNOT be modified once submitted. Please review your work carefully prior to submitting. Please review your work carefully prior to submitting. Once submitted, it will be reviewed by staff for completeness. The AASM Foundation reserves the right to make the appropriate determination for incomplete applications.*

**Face Page**

Information submitted as part of your approved LOI is pre-populated in this form. Please review all the fields in this form and make any changes as necessary. Please note that the information submitted in the approved LOI (e.g., category, key personnel, domain) is final and the applicant will be bound by the content of their approved LOI unless a modification was specifically requested and approved by the AASM Foundation.

*\*Required before final submission*

**Principal Investigator***\**

*Complete the information for the applicant.*

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Email      | Phone      |
| AASM Member Number *If you currently do not have an AASM member number, enter "N/A"*      |
| Institution      |
| Address      |
| City      | State      | Zip Code      |

**Project Information***\**

*Provide information about the project that the applicant is seeking funding for.*

**Strategic Research Grant Category**

*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.*

* Strategic Research Grant: Category I
* Strategic Research Grant: Category II
* Strategic Research Grant: Category III

**Requested Amount**

*Direct and indirect costs must be included in the request amount and must not exceed the category award amount.*

**Length of Project Period (in whole months)**

**Project Title**

 **Project Keywords**

*Please provide 3-5 keywords that are related to your project. This can include the sleep disorder/problem, population, intervention/comparator, methodology, study design and type of research.*

**Sponsoring Organization Contact\***

*This should be an authorized representative from the University's Sponsored Projects, Grants Management Office or Research Administration Office (excluding departmental officials such as the Departmental Chair or Division Chief).*

|  |  |  |
| --- | --- | --- |
| Prefix       | First Name       | Last Name       |
| Position Title      | Phone      | Email      |

**Signed Applicant Sponsoring Organization Page**

*Complete the*[*Applicant Sponsoring Organization Page*](https://foundation.aasm.org/wp-content/uploads/sites/2/2018/08/Applicant-Sponsoring-Organization-Signature-Page.pdf)*and obtain a physical or digital signature from an authorized representative from the University’s Sponsored Projects, Awards Management Office or Research Administration Office (this excludes departmental officials, such as the Departmental Chair or Division Chief).*

**Applicant and Sponsoring Organization Signature Page\***

*Upload the completed and signed Applicant Sponsoring Organization Page.*

**Response to Reviews**

*This section only applies to applicants who are resubmitting an original and unfunded Strategic Research Grant. If your application is not a resubmission, please move to the next page.*

Applicants are allowed a single resubmission of an original and unfunded Strategic Research Grant application within 12 months of receipt of the original application notification. If resubmitting an original and unfunded application, the applicant must still meet all eligibility criteria listed under the Eligibility section of this request for applications. The resubmission MUST include a response to the reviewers of the original application; resubmissions that do not include this response will NOT be reviewed.

Provide your response letter to the critiques from the review of the original application.

**Response Letter to Critiques**

*Upload the Response Letter to Critiques.*

*Formatting Requirements:*

* *Limited to 1 page*
* *Times New Roman 11 pt or 12 pt font required with all margins no less than .50 inches*

**Research Plan and Goals**

*\*Required before final submission*

**A. Abstract**
Provide a succinct and accurate description of the proposed work. It should include the project’s broad, long-term objectives and specific aims.

**B. Research Plan and Goals**
State concisely the goals of the proposed project and plan to achieve those goals. Your description should include the following sections:

1. Background
2. Methods, including evaluation methodology
3. Expected results and deliverables (must include progress reports every 6 months)
4. Discussion of the significance of the research
5. A timeline for the conduct of the project
6. References (not included in the page limit)

**Abstract, Research Plan and Goals\***

*Upload the abstract, research plan and goals as one document.*

*Formatting Requirements:*

* + *Abstract is limited to 200 words maximum*
	+ *Research Plan and Goals is limited to 6 pages total, excluding references.*
	+ *Times New Roman 11 pt or 12 pt fond required with all margins no less than .50 inches.*

**Project Personnel**

*\*Required before final submission*

*Instructions: Information submitted as part of your approved LOI is pre-populated in this form. Please review all the fields in this form and make any changes as necessary. Please note that the information submitted in the approved LOI (e.g., category, key personnel, domain) is final and the applicant will be bound by the content of their approved LOI unless a modification was specifically requested and approved by the AASM Foundation.*

*Project personnel include the principal investigator, mentor(s) and key personnel. National Institutes of Health (NIH) format biosketches and other support pages are required for the principal investigator and mentor(s). NIH format biosketches and other support pages are optional for key personnel.*

***NIH Biosketch****samples can be found here:*[*NIH Sample Biosketch Templates*](https://grants.nih.gov/grants/forms/biosketch.htm)*. Applicants are required to use the current version of the NIH Biosketch Biographical Sketch Format Page.****NIH Other Support Page****format information can be found here:*[*NIH Other Support Page Format*](https://grants.nih.gov/grants/forms/othersupport.htm) *In the Other Support Page, please provide information about all other active support for the principal investigator, mentor(s) and key personnel. This should include overlap statements indicating budgetary, scientific or effort overlap between proposed project and current/pending projects. Overlap statements are required. If no overlap exists between the active projects listed on the Other Support page and the proposed project, please indicate "Overlap: None" on the Other Support Page. Applicants are required to use the current version of the NIH Other Support Format Page.*

**Biosketch and Other Support for Principal Investigator**

**Biosketch for Principal Investigator\***

*Upload Biosketch for Principal Investigator.*

*Formatting Requirements: Limited to 5 pages.*

**Other Support Page for Principal Investigator\***

*Upload Other Support Page for Principal Investigator.*

*Formatting Requirements: No page limit.*

**Biosketch and Other Support for Key Personnel**

Please identify the key personnel for this project. Key personnel include co-investigators and others who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not they receive compensation.

1. **Key Personnel #1**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Institution      |
| E-mail      |
| Project Role      |

1. **Key Personnel #2**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Institution      |
| E-mail      |
| Project Role      |

1. **Key Personnel #3**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Institution      |
| E-mail      |
| Project Role      |

1. **Key Personnel #4**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Institution      |
| E-mail      |
| Project Role      |

1. **Key Personnel #5**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Institution      |
| E-mail      |
| Project Role      |

**Biosketch(es) for Key Personnel**

*Upload the Biosketch(es) of all Key Personnel listed above as one document.*

*Formatting Requirements: Limited to 5 pages per key personnel.*

**Other Support Page(s) for Key Personnel**

*Upload the Other Support Page(s) for all Key Personnel listed above as one document*

*Formatting Requirements: No page limit per key personnel.*

**Letters of Support**

*\*Required before final submission*

The application may include letters of support from your institution, key personnel, collaborators, and other significant contributors. The letters of support can include information on institutional commitment or resources, collaboration or role in the project, and potential or current user of a resource or service proposed in the application.

**Letters of Support\***

*Upload the letters of support as one document.*

*Formatting Requirements:*

* + *Each individual letter of support is limited to 1 page.*
	+ *Times New Roman 11 pt or 12 pt fond required with all margins no less than .50 inches.*

**Budget and Budget Justification**

*\*Required before final submission*

1. **Budget**

Complete a Research & Related (R&R) Budget Form for each year of funding requested. Please use the following link to download the R&R Budget Form: [R&R Budget Form](https://foundation.aasm.org/wp-content/uploads/sites/2/2021/10/R-R-Budget-Form.docx)

**Research and Related (R&R) Budget Form\***

*Upload the completed R&R Budget Form(s) as one document.*

1. **Budget Justification**

The Budget Justification should include the rationale for each item listed as a direct cost in the R&R Budget Form. Salaries (and proportional benefits) should be requested only for time spent on the proposed project. Only include supplies and other purchases that are required for completion of the proposed project.

**Budget Justification\***

*Upload the Budget Justification.*

*Formatting Requirements:*

* *Limited to 2 pages total*
* *Times New Roman 11 pt or 12 pt font required with all margins no less than .50 inches*

**Human Subjects/Animal Research Protection Plan**

*\*Required before final submission*

*Instructions: Please specify what type of subjects are involved in your research proposal and only complete the appropriate section below.*

1. **Type of Subjects:** Choose an item.**\***
2. **Animal Research Protection Plan**

*Only complete this section if the project involves animal research.*

If you selected Animal Research above, an Institutional Animal Care and Use Committee (IACUC) application must be provided.

**Institutional Animal Care and Use Committee Application**

*Upload your IACUC application.*

1. **Human Subjects Research – Exempt Protection Plan**

*Only complete this section if the project involves human subjects research that are exempt from Institutional Review Board review.*

If you selected Human Subjects Research Proposed - Categorized as Exempt, please provide the following:

**A. Risk to Human Subjects:**
a. Human subject involvement and characteristics
b. Source of materials
c. Potential risks

* i. Proposed involvement
* ii. Sample size, age range and health status
* iii. Inclusion/exclusion criteria
* iv. Rationale for recruiting special categories (children, pregnant women etc.)
* v. Collaborating sites (if any)

**B. Adequacy of protection against risks**
a. Recruitment and informed consent
b. Planned procedures for minimizing risks and protecting against risks

**C. Potential benefits of the proposed research to human subjects and others**
a. Discuss the favorable risk-to-benefit ratio of the proposed research study

**D. Importance of knowledge to be gained**
a. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research

**E. Data and safety monitoring plan (if any)**

**F. An exempt approval letter from your institution must be provided**

**Human Subjects Research - Exempt Protection Plan**

*Upload one document containing the above items A-F*

*Formatting Requirements:*

* *Limited to 3 pages*
* *Times New Roman 11 pt or 12 pt font required with all margins no less than .50 inches.*
1. **Human Subjects Research – Non-Exempt Protection Plan**

*Only complete this section if the project involves human subjects research that is not exempt and requires Institutional Review Board review.*

If you selected Human Subjects Research Proposed - Non-Exempt, please provide the following:

**A. Risk to Human Subjects:**
a. Human subject involvement and characteristics
b. Source of materials
c. Potential risks

* i. Proposed involvement
* ii. Sample size, age range and health status
* iii. Inclusion/exclusion criteria
* iv. Rationale for recruiting special categories (children, pregnant women etc.)
* v. Collaborating sites (if any)

**B. Adequacy of protection against risks**
a. Recruitment and informed consent
b. Planned procedures for minimizing risks and protecting against risks

**C. Potential benefits of the proposed research to human subjects and others**
a. Discuss the favorable risk-to-benefit ratio of the proposed research study

**D. Importance of knowledge to be gained**
a. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research

**E. Data and safety monitoring plan (if any)**

**Human Subjects Research – Non-Exempt Protection Plan**

*Upload one document containing the above items A-E*

*Formatting Requirements:*

* *Limited to 3 pages*
* *Times New Roman 11 pt or 12 pt font required with all margins no less than .50 inches.*

**Demographic Questionnaire**

The following questionnaire is **OPTIONAL** for all applicants and is not considered part of the 2023 Strategic Research Grant: Hypopnea Scoring Criteria application. Applicant responses are not used in the decision-making process and will not be provided to reviewers.

**How will the information be used?**

• The data collected will be used to help us understand the diversity of applicants and to inform the development of targeted equity and diversity efforts in the sleep field.

• The information provided may be shared publicly as part of aggregated data on the combined pool of AASM Foundation applicants and grant recipients.

**Will my individual responses be kept confidential?**

• Your individual responses will not be shared with grant reviewers or be used by AASM Foundation leadership to make funding decisions.

• AASM Foundation staff and leadership agree to maintain confidentiality of all application information. The information provided may be shared publicly as part of aggregated data on the combined pool of AASM Foundation applicants and grant recipients. The AASM Foundation will take the utmost measures to ensure confidentiality and security of the information provided.

**Demographic Questions**

1. **Age (select one)**
* 20-24 years
* 25-29 years
* 30-34 years
* 35-39 years
* 40-44 years
* 45-49 years
* 50-54 years
* 55-59 years
* 60-64 years
* 65-69 years
* 70-74 years
* 75-79 years
* 80-84 years
* 85 years and over
* Prefer not to respond
1. **Race and Ethnicity (check all that apply)**
* Black/African American/African
* Asian/Asian American/Pacific Islander
* White/Caucasian/European
* Latino/Latina/Latinx/Hispanic
* Native American/American Indian/Indigenous
* Other
* Don’t Know
* Prefer not to respond

**If you selected “Other” in question 2, please provide details:**

1. **Gender Identity (select one)**
* Female
* Male
* Non-binary
* Transgender
* Agender/Gender-Neutral
* Don’t Know
* Prefer not to respond
1. **Sexual Orientation (select one)**
* Lesbian or Gay
* Straight, that is, not lesbian or gay
* Bisexual
* Other
* Don’t Know
* Prefer not to respond

**If you selected “Other” in question 4, please provide details:**

1. **Disability (select one)**
* Person with a disability
* Person without a disability
* Don’t Know
* Prefer not to respond
1. **Disadvantaged Background (select all that apply)**
* Were or currently are homeless
* Were or currently are in the foster care system
* Were eligible for the Federal Free and Reduced Lunch Program for two or more years
* Have/had no parents or legal guardians who completed a bachelor’s degree
* Were or currently are eligible for Federal Pell grants
* Received support from the Special Supplemental Nutrition Program for Women, Infants and Children as a parent or child
* Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration Rural Health Grants Eligibility Analyzer, or b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health
* Other disadvantaged background
* None of the above apply
* Prefer not to respond

**If you selected “Other” in question 6, please provide details:**