|  |
| --- |
| 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: Central Disorders of Hypersomnolence Research. 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 Hypersomnia Foundation, Wake Up Narcolepsy, and AASM Foundation general funds.

This is a focused request for applications (RFA) open to projects that 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](https://jcsm.aasm.org/doi/10.5664/jcsm.9326)* and basic, translational, clinical and population research gaps identified by patient advocacy stakeholder groups. 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. **Basic and Translational 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. Examples of research topics that fall under basic translational studies for understanding central disorders of hypersomnolence include, but are not limited to:

1. Research to understand the mechanisms of hypersomnia and excessive daytime sleepiness in specific conditions, so that more targeted therapies can be developed.
2. Understanding the role of the innate and adaptive immune system in the development of narcolepsy and other central disorders of hypersomnolence should herald clinical trials in immune modulating treatments that could attenuate disease severity.
3. Understanding the molecular architecture of the human orexin receptor to inform development and testing of orexin specific therapies.
4. 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.
5. Research that investigates whether data and findings from published basic science sleep research are relevant to or can be applied to further the understanding, diagnosis, or treatment of central disorders of hypersomnolence.
6. **Improvement of Diagnosis for Central Disorders of Hypersomnolence**

Identification of central disorders of hypersomnolence currently poses a challenge, and there is a need to improve its diagnosis in sleep medicine practice and routine clinical practice. Examples of research topics that fall under the improvement of diagnosis for central disorders of hypersomnolence include, but are not limited to:

1. Development of novel diagnostic tools and methodologies.
2. Develop extended sleep studies needed for better diagnosis of idiopathic hypersomnia.
	* In-house sleep clinic protocols for extended sleep studies to enable better phenotyping of hypersomnias (long sleep type, disrupted sleep, total 24+ hour sleep time).
	* Evaluate home extended sleep studies, wearable EEGs/sleep monitors, etc.
3. **Pharmacologic Treatments for Central Disorders of Hypersomnolence**

There is a need for studies that directly compare different medications used to treat central disorders of hypersomnolence across the lifespan. Examples of research topics that fall under pharmacological treatments for central disorders of hypersomnolence include, but are not limited to:

1. 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.
2. Well-designed studies evaluating the following:
	* Commonly used traditional stimulants for central disorders of hypersomnolence, and/or
	* Selective serotonin reuptake inhibitors/serotonin and norepinephrine reuptake inhibitors cataplexy treatments for people with narcolepsy type 1.
3. Prospective clinical trials for drugs widely used for treating cataplexy. The low cost of this therapy is attractive, and it is already commonly used across the world.
4. Research and develop front-line treatments for narcolepsy and other central disorders of hypersomnolence.
5. High quality randomized controlled trials for pediatric patients with central nervous system hypersomnias since children and adolescents may react differently to medications for hypersomnolence than adults, and side effect profiles can vary based on patient age.
6. Studies to discover how oxybates and other hypersomnia medicines work and to help predict which particular people with central disorders of hypersomnolence will most likely benefit from each of these medicines.
7. **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 people with central disorders of hypersomnolence. Examples of research topics that fall under patient-centered outcome measures for central disorders of hypersomnolence include, but are not limited to:

1. 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.
2. 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 people’s lifestyles.
3. Evaluate treatments for narcolepsy and other central disorders of hypersomnolence in regard to patient satisfaction, ability to adhere and continue treatment, and overall quality of life.

***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*

1. **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. Examples of research topics that fall under behavioral and psychological treatments for central disorders of hypersomnolence include, but are not limited to:

1. Evaluating cognitive behavioral therapy (in-person, online), sleep scheduling, naps, exercise, and specific diets for furthering medication effects and/or demonstrating independent treatment benefit.
2. **Disparities and Health Access Equity Research for Central Disorders of Hypersomnolence**

It is well-known that sleep disturbances and deficiencies affect disadvantaged populations, which lead to disproportionate sleep health disparities in the United States. However, little is known on how to best find, diagnose, and treat individuals with central disorders of hypersomnolence, particularly those from underrepresented communities. This is further hampered by lack of knowledge on central disorders of hypersomnolence among health care providers and the public, which can lead to delayed diagnosis, treatment, and support for people with central disorders of hypersomnolence. Examples of research topics that fall under disparities and health access equity research for central disorders of hypersomnolence include, but are not limited to:

1. Develop a sleep disorder screening tool that is inclusive of all central disorders of hypersomnolence and can be used by the public, for example, on a website, where patients can answer a list of questions and receive information on a possible diagnosis, including information on how to follow up with a sleep medicine specialist and connect with patient advocacy groups.
	* Any screening tool developed should consider whether there is a need for customization for people from diverse backgrounds.
	* Delivery of the tool may differ by group.
2. Quantify access to diagnosis and treatments for less common sleep disorders (e.g., central disorders of hypersomnolence) for people from diverse backgrounds.
3. Initiatives to accurately collect demographic fields in electronic health records to measure current diversity and health equity and lay foundation for further health equity research and improvement.
4. Increase outreach to historically underserved populations, both patients and future providers.

**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*

**Project Information***\**

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

**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.*

**Research Domain**

*Only one research domain may be selected.*

* Basic and Translational Studies for Understanding Central Disorders of Hypersomnolence
* Improvement of Diagnosis for Central Disorders of Hypersomnolence
* Pharmacologic Treatments for Central Disorders of Hypersomnolence
* Patient-Centered Outcome Measures for Central Disorders of Hypersomnolence
* Behavioral and Psychological Treatments for Central Disorders of Hypersomnolence
* Disparities and Health Access Equity Research for Central Disorders of Hypersomnolence

**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

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

**Requested Amount**

*Direct and indirect costs must be included in the request amount and must not exceed the category award amount. This amount needs to match what is included in the R&R Budget Form.*

**Contact Principal Investigator***\**

*Complete the information for the Principal Investigator who will be the point of contact for the proposed project.*

|  |  |  |  |
| --- | --- | --- | --- |
| 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      | Country      | Zip Code      |

**Multi-Principal Investigator***\**

*Complete the information for multi-Principal Investigators, if any.*

**Does this proposal have multiple Principal Investigators?**

* Yes
* No

 **Multi-Principal Investigator #1**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Email      | Phone      |
| Institution      |
| Address      |
| City      | State      | Country      | Zip Code      |

**Multi-Principal Investigator #2**

|  |  |  |  |
| --- | --- | --- | --- |
| Prefix       | First Name       | Last Name       | Degree/Credentials       |
| Position Title      | Email      | Phone      |
| Institution      |
| Address      |
| City      | State      | Country      | Zip Code      |

**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/multi-principal investigators and key personnel. National Institutes of Health (NIH) format biosketches and other support pages are required for the principal investigator/multi-principal investigators and all key personnel.

**NIH Biosketch** samples and format information 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. Please use the following link to download the current version of the NIH Biosketch Template: [NIH Biosketch Template](https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx)

**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/multi-principal investigators 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. Please use the following link to download the current version of the NIH Other Support Format Page: [NIH Other Support Format Page](https://grants.nih.gov/grants/forms/othersupport.htm)

**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)

The total amount listed on the R&R Budget Form **must** match the funding request amount on the Face Page of this application form. If the project is multi-year, a separate budget form must be submitted for each year of the project.

**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 Protection Plan**

*Complete this section if the project involves human subjects research. This applies to projects that are exempt from Institutional Review Board review and projects that are non-exempt from Institutional Review Board review.*

If you selected Human Subjects Research Proposed - Exempt OR 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 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: Central Disorders of Hypersomnolence Research 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:**