



COVID-19 & Dental Sleep Medicine – 2020 Research Award

ISSUE DATE:	August 31, 2020
LETTER OF INTENT DUE DATE:	UPDATED: October 30, 2020
FULL APPLICATION DUE DATE:	UPDATED: January 28, 2021
AWARD SELECTION NOTIFICATION	UPDATED: March 15, 2021
PERIOD OF PERFORMANCE:	Project Timeline can be 1 to 2 years
AMOUNT OF AWARD	Up to \$25,000 per award
APPLICATION FORMAT:	Electronic submission as one document with all materials and inquiries sent by email to the address below. If confirmation of submission is not received within three days of submission, contact the AADSM at 630-686-9877. NOTE: An original of Form 1 must be mailed.
CONTACT PERSON:	Heather Montague, Research and Policy Development Manager 1001 Warrenville Road, Suite 175 Lisle, IL 60532 Phone: 630-686-9877 Email: hmontague@aadsm.org

The American Academy of Dental Sleep Medicine (AADSM) is pleased to announce the 2020 COVID-19 Dental Research Award. This award will fund clinical research addressing the current COVID-19 pandemic with clear relevance to the practice of dental sleep medicine. Specifically, proposals to answer the following research questions will be considered:

1. Dental Sleep Medicine practice modifications during the COVID-19 pandemic
 - Use of telemedicine
 - Strategies to reduce spread of COVID-19 while delivering OAT
 - Impact of practice closures on patient care and practice economics
 - Practice outcomes/best practices in dental sleep medicine practices impacted by COVID-19
2. PAP vs. OAT during the COVID-19 pandemic
 - Comparison of OAT vs. CPAP use on transmission of COVID-19
 - Use of PAP vs. OAT after recovery from COVID-19

Please note the following restrictions:

- The goal of this award is to broadly advance research in dental sleep medicine. As a result, findings must be relevant to the field beyond the use of a specific, patented or branded oral appliance. As stated below, the applicant must not have a financial conflict of interest or incur significant financial benefit from the proposed work above and beyond the work itself. If a specific device will be tested, the device must be named in

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the research methods section of the application, the technology must be described in general terms and with sufficient detail for reviewers to evaluate the relevance to the field in general, and the investigator(s) must clearly attest that there is no financial conflict of interest.

- Requests for bridge funding will not be considered.

Letter of Intent

A Letter of Intent (LOI) is **required** prior to submission of a full application. A LOI is a brief description of the proposed project and will be used to evaluate how well the project responds to the research questions proposed in the RFA.

The LOI must include the following components:

- A 1-page cover letter including the following information:
 - Title of the project
 - Name, institutional affiliations and roles for each member of the project team
 - Topic area(s) (From the 5 topic areas listed above) addressed by the application
 - A brief statement (300 words or less) describing how the proposed project meets the objectives of this RFA and the potential impact of the proposed work on dental sleep medicine.
- Principal Investigator's (PI, the lead investigator) current biosketch (see Form 3, below; up to 2 pages total) – a biosketch is a brief description of the lead investigator's credentials and research background
- List of any other current sources of research support, including the source, amount, and short description of each project (150 words or less)
- 1-2 page synopsis of the proposed project including:
 1. A brief summary of relevant scientific literature supporting the application,
 2. The proposed study's specific aims,
 3. A brief summary of the study methods, and
 4. A description of the data analysis plan

Criteria for LOI review:

The following criteria will be considered in determining whether the applicant will be invited to submit a full application for consideration:

1. Topical responsiveness and potential impact
2. Feasibility of the planned research
3. Overall quality of the methods and analytic plan
4. Appropriateness of the investigators, consultants and other research partners to conduct the proposed work

The Letter of Intent should be emailed to Heather Montague at hmontague@aadsm.org and is due no later than **11:59 pm Central time October 30, 2020**. Applicants will be notified whether they will be invited to submit a full application by December 9, 2020. If the LOI is not approved, the applicant may NOT submit an application for the award.

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Eligibility

- The applicant must possess a master's level degree or higher.
- The applicant must have access to the necessary facilities and resources to perform the proposed work.
- Projects must be performed by United States- or Canadian-based investigators and institutions.
- The applicant must not have a financial conflict of interest or incur significant financial benefit from the proposed work above and beyond the work itself.

Structure of Award

This award is a contract between the AADSM and the recipient and/or institution. If the principal investigator (PI, leader of the research project) changes locations during the course of the award, the PI must seek approval from the AADSM in advance to request transfer of the award. Use of funds is limited to direct research activities (funds cannot be used for investigator travel or meeting expenses). Indirect costs paid to an institution or practice will be limited to 8%.

Grant funds may not be used for:

- (1) Salary support for the PI or faculty-level collaborators (Funds may be used for research staff or statisticians to carry out the project)
- (2) Office supplies or communication costs unless specifically justified as uniquely needed for the proposed work
- (3) Meals or travel, including to conferences, except as required to collect data or perform specific project-related activities
- (4) Professional education or training for investigators
- (5) Computers or audiovisual equipment, unless specifically justified as uniquely needed for the proposed work
- (6) Manuscript preparation and submission fees

Principal Investigators and co-investigators at academic partner institutions are expected to have salary support from their institutions, practices or other funding sources sufficient to allow them time to direct the project and conduct the research.

In response to this RFA, projects that are currently funded by another awarding body will not be considered; however, requests to provide matching funds for projects that require such funds from another awarding body will be considered.

Proposals

Proposals are encouraged, but not required, to include collaborative approaches, when appropriate, drawing upon the relative strengths and contributions of each collaborator.

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Payment Structure

The payment structure for these awards is outlined in the chart below:

Payment – At execution of Contract	90%
Payment - Upon receipt and approval of Final Report	10%
Reporting – Progress reports	Every six months
Reporting – Final report	Within 90 days of completion

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

Duration of Award

The duration of the award may be up to 2 years. In addition to the project plan and the budget, a timeline which clearly states the expected duration of the proposed project and major milestones should be provided as part of Form 2.

Award Review Criteria and Process

An award review committee appointed by the AADSM Board of Directors will evaluate and score all submitted proposals. The AADSM Board of Directors will make the final determination regarding award recipients. Factors that will be taken into consideration include the presence of resources necessary to complete the study (including the commitment and experience of the institution), feasibility and scientific merit of the research plan, environment, the appropriateness of the proposed research to the AADSM mission, and the anticipated relationship between the funds provided and expected outcomes.

Deliverables and Outcome Measure

Outcomes evaluation is an essential component of this award. All proposals must identify the goals and appropriate outcome measures (ways to measure the results) of the research. The outcomes should align with the goals and objectives stated in the applicant’s proposal for this award. The AADSM requires that the research sponsored under this award lead to the submission of original research for publication and that at least one of the manuscripts resulting from this work be submitted for publication in the *Journal of Dental Sleep Medicine* and that the work be presented in abstract form at the AADSM Annual Meeting.

The outcome measures and deliverables should be clearly stated in Form 2. The applicant must submit progress reports describing project activities and results as described above during the project period. Failure to meet the deliverables or submit the progress reports may result in termination of project funding.

Completion of the Application

Please read these instructions for completion of the application carefully.

- Applications must be received by the AADSM national office by **11:59 pm Central time, January 28, 2021**. All applications must be submitted electronically.
- An original of Form 1 (Face Page) must be signed in ink by the Applicant and a representative of the Sponsoring Organization (e.g. “sponsored projects office” of the

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lead investigator's institution or owner of the dental practice where the work will be performed) and mailed to the AADSM office within 10 business days of the application deadline.

- The six forms of the application that follow must be completed and sent in a Microsoft Word document format via email to hmontague@aadsm.org.

The entire application (excluding the budget) may not exceed 13 pages. The required forms for the application include:

Form	Description	Page Maximum
Form 1	Face Page	1 Page
Form 2	Goals and Activities Planned, including a project timeline	6 Pages (excluding citations)
Form 3	Applicant biosketch and personnel biosketches from key members of the research team, including all sites in multi-center research applications	2 Pages (each)
Form 4	Budget and justification	No limit
Form 5	Human Subject Protection Plan (HSPP), including the institutional review board who will provide oversight of the project	3 Pages
Form 6	Copy of the LOI Approval Memo	

Human Subject Protection Plan (HSPP)

The applicant will be responsible for obtaining Institutional Review Board (IRB) approval for the project and for safeguarding patient safety and confidentiality. An institutional review board (IRB) is a group that oversees and monitors research in order to ensure that human subjects (who participate in the research) are kept safe and that their rights are protected. An IRB may function within the university or institution where the work is performed or may be a third-party (e.g. commercial IRB). The PI should contact the IRB at their home institution or the institution where work will be performed to determine requirements for IRB approval of the projects. IRB approval is required for all human subjects research, even if the institution where the work is performed does not have their own IRB.

Form 5 should be used to outline the Human Subject Protection Plan (HSPP) and is required as part of the application. Plans for addressing risks to human subjects, adequacy of protection against risks and potential benefits of proposed research and importance of knowledge to be

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gained should be provided. Reviewers will consider the proposed human subjects protection plan as a component of feasibility of the proposed research. The IRB letter of approval for the specified project must be on file with the AADSM office prior to initiation of any contracts or distribution of funds. No funds will be released for the project without receipt of written approval by an IRB. Failure to receive and maintain approval from an IRB or Human Subjects Committee will result in retraction of the award.

Award Notification

The AADSM Board of Directors will notify the applicants of their decision by **March 15, 2021**.

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Letter of Intent Cover Page

Primary Investigator - Attach current biosketch (up to 2 pages total)		
Name:		
Institution/Practice:		
Title of Project:		
Team Members		
Name:	Role:	Institution/Practice:
Name:	Role:	Institution/Practice:
Name:	Role:	Institution/Practice:
Name:	Role:	Institution/Practice:
Name:	Role:	Institution/Practice:

Research Domain of your proposal: (check the one that applies)

1. Dental Sleep Medicine practice modifications during the Covid-19 pandemic

2. PAP vs. OAT in the era of COVID-19

Below, please provide a brief statement (300 words or less) about how the proposed project meets the objectives of this RFA and the potential impact of the proposed work on clinical care for patients with sleep disorders.

Please list of any other current sources of research support, including the source, amount, and short project description (150 words or less).

Attach a 1-2 page synopsis of the proposed project including:

1. A brief summary of relevant literature supporting the application,
2. The proposed study's specific aims,
3. A brief summary of the study methods, and
4. A description of the data analysis plan

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Full Application Checklist

The following items must be provided with your application to the AADSM for consideration of the award.

<input type="checkbox"/> Form 1 – Face Page <i>(limited to 1 page)</i>
<input type="checkbox"/> Contact information for applicant
<input type="checkbox"/> Host institution contact information - include individual for contract negotiation
<input type="checkbox"/> Signature of Applicant
<input type="checkbox"/> Signature of Institution Representative
<input type="checkbox"/> Form 2 – Goals and Activities Planned <i>(limited to 6 pages)</i>
<input type="checkbox"/> Form 3 – Biosketches <i>(limited to 2 pages per person)</i>
<input type="checkbox"/> Form 4 – Budget
<input type="checkbox"/> Form 5 – Human Subject Protection Plan <i>(limited to 3 pages)</i>
Plan addressing risks to human subjects
<input type="checkbox"/> Form 6 – Copy of the LOI Approval Memo

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Form 1 – Face Page

APPLICANT INFORMATION	
Applicant Full Name:	
Applicant Institution/Practice:	
Applicant AADSM Member Number:	
Street Address:	
City, State/Province, Zip/Postal Code:	
Telephone:	Email:
TITLE OF PROJECT	
HOST INSTITUTION/OWNER OF PRACTICE	
Contact Person:	
Position:	
Street Address:	
City, State/Province, Zip/Postal Code:	
Telephone:	Email:
I certify that all of the statements in this application are true to the best of my knowledge, and I agree to comply with all the terms and conditions of the contract if an award is issued as a result of this application.	
Signature of Applicant:	Date:
Print Name:	
Sponsoring Organization Representative *:	Date:
Print Name:	

*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) or the owner of the dental practice. An original of Form 1 (Face Page) must be signed in ink by the Applicant and a representative of the Sponsoring Organization and mailed to the AADSM office within 10 business days of the application deadline.

Mail original to:
American Academy of Dental Sleep Medicine
1001 Warrenville Road, Suite 175
Lisle, IL 60532
Attn: Heather Montague

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Form 2 – Goals and Activities Planned

GOALS AND ACTIVITIES PLANNED	
Title of Project:	Duration of Project:
Applicant Name:	

Use this page and up to five additional pages to describe your research plan. Your description should include the following sections:

1. Abstract (200 words maximum)
2. Background
3. Methods, including evaluation methodology
4. Outcome measures and deliverables (must include 6-month progress reports)
5. Discussion of the significance of the research
6. A timeline for the conduct of the project
7. Citations (not included in page limit)

Text should be single spaced with minimum font-size of Arial 11 pt, or Times New Roman 12 pt.

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Form 3 – Biosketches

BIOSKETCH	
TITLE OF PROJECT	
Applicant Name:	Applicant Position Title:

Use this page and one additional page per person, to provide background information about the applicant and key members of the research team, including all sites in multi-center research applications.

Education/Training:

(Begin with baccalaureate and include dental/medical school, residency and fellowship and graduate training)

Institution and Location	Degree (if any)	Years	Field of Study

Positions and Honors:

Selected Peer-reviewed Publications:

Current and Prior Research Funding:

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Form 4 – Budget and Budget Justification

BUDGET and BUDGET JUSTIFICATION				
Title of Project:			Dates of Project:	
Applicant Name:			Institution/Affiliation:	
SALARIES				
Person	Title	Base Salary	Hours on Project	Total
1.				
2.				
3.				
FRINGE BENEFITS				
Person			Title	Total
1.				
2.				
3.				
SUPPLIES: (itemize and provide brief justification)				Amount
OTHER: (itemize and provide brief justification)				Amount
Total Direct Costs				
Indirect Costs (must not exceed 8% of direct costs)				
Total Funding Request (must not exceed \$25,000)				

Budget Justification (up to 2 additional pages) should include the rationale for each item listed as a direct cost in the table above. 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.

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Form 5 – Human Protection Plan / Institutional Animal Care and Use Committee (IACUC)

All applications should specify one of the three scenarios provided below. If you are unsure of which scenario best applies to your research, if applicable, contact your institution's IRB.

Check one of the following applicable scenarios for the proposed research:

- | | | |
|-------|--|--------------------------|
| (I) | No Human Subjects Research Proposed | <input type="checkbox"/> |
| (II) | Human Subjects Research Proposed – categorized as Exempt | <input type="checkbox"/> |
| (III) | Human Subjects Research Proposed – Non-exempt | <input type="checkbox"/> |

If Response is Scenario (I): It is generally applicable to studies involving animal experimentation. In this case, plan for IACUC application should be provided under category addressing "IACUC/Humane Treatment of Animals."

If Response is Scenario (II): Plans for addressing risk to human subjects, adequacy of protection against risks, and potential benefits of proposed research and importance of knowledge to be gained should still be provided as requested in required response for scenario (III). Upon finding, the local IRB determination of exemption and approval of this specific study under such an exempt status should be provided to the AADSM office.

If Response is Scenario (III): The following items should be addressed in the award application.

All scenarios should contain the information pertaining to the following categories, which is required:

- 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 process for obtaining informed consent from participants
 - 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)