BUSINESS ASSOCIATE AGREEMENT

This BUSINESS ASSOCIATE AGREEMENT ("BAA") is entered into as of __________ ("Effective Date") by and between ____________________________________________ ("Covered Entity") and American Academy of Sleep Medicine ("Business Associate" or "BA"). Covered Entity and BA may each be referred to herein as a "Party" or collectively as the "Parties." This BAA supersedes any previous BAA between the Parties.

1. **Background and Purpose.** In the course of inspecting Covered Entity for accreditation purposes, BA may be given access to Protected Health Information ("PHI"). The parties have entered into this BAA to ensure compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), codified at 45 C.F.R. Part 160 and Part 164, subparts A and C (the “Security Rule”), subparts A and D (the “Breach Notification Rule”), and subparts A and E (the “Privacy Rule”), all as applicable and as amended by Subtitle D of the Health Information Technology for Economic and Clinical Health ("HITECH") Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and as clarified by any and all amendments, regulations, and guidance thereto (collectively, “the Rules”).

2. **Definitions.** Unless otherwise defined in this Agreement, all capitalized terms shall have the meanings ascribed to them in the Rules.

3. **Obligations of the Parties with Respect to PHI.**

   3.1. **Obligations of Business Associate.** With regard to its use and disclosure of PHI, BA agrees that:

   a. BA will not use or further disclose PHI other than as permitted or required by this BAA or as Required by Law. BA shall not use or disclose PHI created, received, maintained, or transmitted for or on behalf of Covered Entity in any manner that would constitute a violation of HIPAA if so used or disclosed by Covered entity (except as set forth in Section 3.2 of this BAA).

   b. BA shall implement and use appropriate safeguards to prevent use or disclosure of PHI other than as permitted or required by this BAA or as Required By Law, and comply, where applicable, with the HIPAA Security Rule with respect to electronic PHI. BA acknowledges and agrees that the administrative, physical and technical safeguards requirements of 45 C.F.R. §§ 164.308, 164.310 and 164.312 shall apply to the BA in the same manner that such sections apply to the Covered Entity.

   c. BA will ensure that any Subcontractor, including, without limitation, a Subcontractor that is an agent under applicable law, that creates, receives, maintains, or transmits PHI on behalf of the BA, enters into a written agreement with BA that meets the requirements of 45 C.F.R. §§ 164.504(e) and 164.314(a)(2) and obligates the Subcontractor to comply with the same restrictions and conditions that apply to the BA with respect to such PHI.

   d. BA will document any and all disclosures of PHI by BA or its Subcontractors or agents as well as any other information related to such disclosures of PHI that would be required for Covered Entity to respond to an Individual’s request for an accounting of disclosures in accordance with 45 C.F.R. § 164.528. Within ten (10)
business days of receipt of a request from Covered Entity for such documentation and information, BA will make such documentation and information.

e. Within five (5) business days of a request by Covered Entity for access to PHI about an Individual contained in any Designated Record Set maintained by BA, BA shall make available to Covered Entity such PHI as necessary to allow Covered Entity to comply with its obligations set forth at 45 CFR § 164.524.

f. Within five (5) business days of a request by Covered Entity for the amendment of PHI about an Individual contained in any Designated Record Set maintained by BA, BA shall make available to Covered Entity such PHI as necessary to allow Covered Entity to comply with its obligations set forth at 45 CFR § 164.526.

g. BA will make available to the Secretary of the U.S. Department of Health and Human Services (“HHS”) any and all internal practices, books, and records of BA relating to the use and disclosure of PHI, for purposes of determining Covered Entity’s compliance with the Privacy Rule.

h. BA will, as required by the “minimum necessary” requirements of HIPAA at 45 C.F.R. § 164.502(b)(2), only request, use, and disclose the minimum amount of PHI that is necessary to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the BAA.

i. BA will not, directly or indirectly, receive remuneration in exchange for Covered Entity’s PHI unless BA or Covered Entity has obtained an authorization from the subject Individual(s), which complies with all applicable requirements, or otherwise permitted by the Rules. BA may not rely on any of the foregoing exceptions without advance notice to Covered Entity describing the types of circumstances and the applicable exceptions to be relied upon by BA.

j. To the extent the BA is to carry out one or more of Covered Entity’s obligation(s) under Subpart E of 45 CFR Part 164, BA agrees to comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).

k. BA will not sell PHI and Electronic Health Records or use or disclose PHI for marketing or fundraising purposes as set forth in 42 U.S.C. § 17935(d) or 42 U.S.C. § 17936(a), respectively.

3.2. Permitted Uses and Disclosures of PHI by BA. Except as otherwise specified in this BAA, and to the extent permitted by the Rules, BA may make any and all uses and disclosures of PHI in its possession necessary to perform its obligations under the BAA and may: (a) use the PHI for its proper management and administration or to carry out its legal responsibilities; and (b) disclose the PHI to a third party for the purpose of BA’s proper management and administration or to carry out the legal responsibilities of BA, provided that the disclosure is Required By Law or that BA has obtained reasonable assurances from the third party to whom PHI is to be disclosed that the PHI will be held confidentially and the third party has agreed to notify BA regarding any instances of which it becomes aware in which the confidentiality of the information has been breached.
3.3. **Obligations of Covered Entity.**

a. Covered Entity agrees to notify BA of any restrictions on uses and disclosures of PHI to which Covered Entity agrees with any Individual that will materially restrict BA’s use and/or disclosure of that PHI under this BAA.

b. Covered Entity agrees to notify BA of any changes in, or revocation of, permission by an Individual to use or disclose PHI that will materially restrict BA’s use and/or disclosure of that PHI under this BAA.

c. Covered Entity agrees to notify BA of any changes to its Notice of Privacy Practices that will materially restrict the BA’s use and/or disclosure of PHI under this BAA.

3.4. **Reporting Requirements.**

a. BA will, without unreasonable delay, but in no event later than five (5) business days after becoming aware of any use or disclosure of PHI in violation of this BAA (each, an “Unauthorized Use or Disclosure”), report such Unauthorized Use or Disclosure to Covered Entity.

b. BA will, without unreasonable delay, but in no event later than five (5) business days after becoming aware of any Security Incident, report it to Covered Entity.

c. BA will, without unreasonable delay, but in no event later than five (5) business days after becoming aware of a Breach of Unsecured PHI, provide to Covered Entity notice of the Breach of Unsecured PHI. BA shall reasonably cooperate with Covered Entity as may be necessary to allow Covered Entity to provide notification of the Breach of Unsecured PHI to as required by the Breach Notification Rule.

3.5. **HIPAA Amendments.** Any future amendments to HIPAA affecting Business Associate agreements are hereby incorporated by reference into this Agreement as if set forth in this Agreement in their entirety, effective on the later of the effective date of this Agreement or such subsequent date as may be specified by HIPAA.

4. **Indemnification.**

4.1. To the extent permitted by law, each Party (the “Indemnifying Party”) shall indemnify and hold harmless the other party (the “Indemnified Party”), its officers, directors, employees and agents, from and against, and, at the Indemnified Party’s request, defend the Indemnified Party against, any and all claims, damages, losses, liabilities, costs and expenses (including reasonable attorney’s fees) arising out of or resulting from the grossly negligent or the intentional acts or omissions of the Indemnifying Party, its employees, or its agents that result in material violations of this BAA. Each Indemnified Party shall fully cooperate with the Indemnifying Party in all matters within the scope of this section.
5. **Insurance.**

5.1. Business Associate shall procure and maintain during the term of this BAA insurance with coverage for Breaches of Unsecured PHI. Business Associate shall promptly notify Covered Entity in the event of a lapse, cancellation, or material modification of such coverage.

6. **Term and Termination.**

6.1. This BAA shall commence on the Effective Date and expire when Covered Entity no longer uses BA to accredit the sleep center / laboratory facilities. Covered Entity may terminate its relationship with BA if it determines that BA has violated a material term of this BAA. The rights and responsibilities of BA under this BAA shall survive expiration or earlier termination.

6.2. Upon expiration or earlier termination of its relationship with Covered Entity, BA shall, if feasible, return or destroy all of the PHI that BA, BA’s agent, or BA's Subcontractor still maintains in any form, and shall retain no copies of such information. Notwithstanding the foregoing, if BA determines that such return or destruction of any PHI is not feasible, BA shall extend the protections of this BAA to such PHI and shall limit further uses and disclosures of such PHI to those purposes that make the return or destruction of the PHI infeasible.

7. **Miscellaneous.**

7.1. **Survival.** The obligations imposed on BA pursuant to this BAA with respect to PHI shall survive expiration or earlier termination of this BAA and continue indefinitely solely with respect to PHI that BA, BA’s agent, or BA’s Subcontractor, retains in accordance with Section 4.2.

7.2. **No Third-Party Beneficiaries.** Except as specifically set forth herein, nothing in this BAA shall confer upon any person other than the Parties any rights, remedies, obligations or liabilities whatsoever.

7.3. **Privileges and Protections Not Waived.** Nothing herein shall be construed as waiver of applicable legal or other privileges or protections held or enjoyed by either Party.

7.4. **Amendment.** This BAA shall not be amended except by the mutual written agreement of the Parties.

7.5. **Assignment.** Neither Party may assign any of its rights or obligations under this BAA without the prior written consent of the other Party.

7.6. **Notice.** Any notices required under this BAA shall be deemed effective on the third business day following transmission via electronic mail (“email”), First Class Mail or recognized national courier to the individuals listed on the signature page herein or such other addresses as the Parties subsequently may provide by notice.
IN WITNESS WHEREOF, each of the undersigned has caused this BAA to be executed in its name and on its behalf by its duly authorized representative. By signing below, the Parties acknowledge that they have read, understand, and agree to comply with the terms and conditions of this BAA.

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