

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. It will not use or further disclose PHI other than as permitted or required by this BAA or as required by law. BA shall implement and use appropriate safeguards, and comply, where applicable, with the HIPAA Security Rule with respect to electronic protected health information and documentation requirements. BA acknowledges and agrees that the administrative, physical and technical safeguards requirements of 45 CFR Sections 164.308, 164.310 and 164.312 shall apply to the BA in the same manner that such sections apply to the Covered Entity.
 - b. It will use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this BAA.
 - c. It will report to Covered Entity any use or disclosure of PHI in violation of this Agreement of which BA becomes aware.
 - d. It will ensure that any agents, including a subcontractor, to whom it provides PHI on behalf of Covered Entity, agrees to the same restrictions and conditions that apply to the BA with respect to such information. BA shall ensure that any agent, including a subcontractor, to whom it provides PHI agrees in writing to implement reasonable and appropriate safeguards to protect it; and report to the Covered Entity any security incidents of which it becomes aware.
 - e. It will document any and all disclosures of PHI by BA or its agents, including subcontractors, 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

and will make such documentation and disclosure available to the Covered Entity.

- f. It will, subject to any applicable privilege, following consultation with Covered Entity, 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 or its agents, including subcontractors, relating to the use and disclosure of PHI, for purposes of determining Covered Entity’s compliance with the Privacy Rule.
- g. It will notify Covered Entity of any and all requests by the Secretary of HHS for information prior to any release of information thereunder.
- h. It will, as required by the HITECH Act, comply with 45 C.F.R. 164.308, 164.310, 164.312, and 164.315 of the Security Rule.
- i. It will, as required by the HITECH Act, determine the Minimum Necessary PHI to be disclosed for uses, disclosures or requests of or for Covered Entity’s PHI, other than those exempt from the Minimum Necessary requirement specified in 45 C.F.R. 164.502(b)(2), in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the BAA. To the extent practicable and consistent with the terms of the BAA, the Minimum Necessary shall be the information contained in a Limited Data Set, as defined in 45 C.F.R. 164.514(e)(2).
- j. As required by the HITECH Act, effective not later than six (6) months after the date on which the Secretary publishes applicable final regulations, 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.
- k. 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). BA further agrees not to use or disclose PHI other than as permitted or required by the Agreement, in furtherance of the services provided by BA for Covered Entity, or as required by law. 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. The BA shall secure PHI in accordance with 42 U.S.C. § 17932(h) and the related regulations at 45 CFR Part 14, subpart D, as well as any guidance issued by the Secretary that specifies secure technologies and methodologies such that Unsecured PHI is not maintained by the BA.

- 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; (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 disclosures are 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; and (c) provide Data Aggregation services relating to the Health Care Operations of Covered Entity as permitted by the Privacy Rule.

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 impact in any manner the use and/or disclosure of that PHI by BA under this Agreement. The Parties acknowledge that the HITECH Act requires that Covered Entity must comply with a restriction requested by an Individual if: (1) except as otherwise Required by Law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and (2) the PHI pertains solely to a health care item or service for which Covered Entity has been paid out-of-pocket in full.
- 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 impact in any manner BA's permitted or required uses and/or disclosures of PHI under this BAA.
- c. Covered Entity agrees to notify BA of any changes in its Privacy Practices that will impact in any manner the use and/or disclosure of PHI by BA under this BAA.
- d. Covered Entity agrees to obtain any patient authorizations or consents that may be required under federal or state law in order to transmit PHI to BA and to enable BA to use and disclose PHI as contemplated by this BAA.
- e. If and to the extent that Covered Entity's obligations under 45 C.F.R. 164.528 are amended by Section 13405 of Subtitle D of the HITECH Act (that is, if Covered Entity is required to account for disclosures of PHI for treatment, payment and/or health care operations made through an electronic health record), Covered Entity shall notify BA to maintain an appropriate record of disclosures.

- 3.4. Breach of Unsecured PHI. As required by the Breach Notification Rule, BA shall maintain systems to monitor and detect a Breach of Unsecured PHI, whether in paper or electronic form. BA shall provide to Covered Entity notice of a Breach of Unsecured PHI as soon as possible but not later than ten Business days after the first day the Breach is known. BA shall cooperate with Covered Entity to determine whether the Breach, including instances when an agent or subcontractor has improperly used or disclosed PHI, requires notice to individuals, and will cooperate with Covered Entity as may be necessary to allow Covered Entity to provide notification of the Breach to individuals as required by the Breach Notification Rule. Covered Entity is responsible

for the provision of notice to Individuals in a timely manner, provided that Covered Entity shall consult with BA as needed regarding the details of the notice.

3.5. Prohibition. BA shall not directly or indirectly receive remuneration in exchange for any PHI of an individual, unless:

- a. Covered Entity obtained in accordance with 45 C.F.R. §164.508, a valid authorization from the individual that includes a specification of whether the PHI can be further exchanged for remuneration by the entity receiving the PHI of that individual; or
- b. Any of the exceptions listed in HITECH Act §13405(d)(2) apply.

The parties agree that any of the regulations promulgated by the Secretary pursuant to HITECH Act §13405(d)(3) shall automatically be incorporated into, and apply as of the Applicable Effective Date, to this Agreement.

3.6. Effect of the Rules. To the extent that any relevant provision of the Rules is amended in a manner that materially changes the obligations of BA or Covered Entity under the terms of this BA, the Parties agree to amend this BA in order to give effect to such revised obligations. If the Parties cannot agree on an amendment to this BA, this BA may be terminated by either Party upon (30) days written notice to the other Party, or upon such shorter notice as may be required by applicable law.

4. Term and Termination.

- 4.1. This BAA shall terminate 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 termination.
- 4.2. Upon termination of its relationship with Covered Entity, BA shall, if feasible, return or destroy all of the PHI that BA still maintains in any form, and shall retain no copies of such information. If such return or destruction is not feasible, BA shall extend the protections of this BAA to the PHI and shall limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

5. Miscellaneous.

- 5.1. Survival. The obligations imposed on BA pursuant to this BAA with respect to PHI and EPHI shall survive termination of this BAA and continue indefinitely solely with respect to PHI that BA or its agents, including subcontractors, retain in accordance with Section 4.2.
- 5.2. 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.
- 5.3. 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.

- 5.4. Amendment. This BAA shall not be amended except by the mutual written agreement of the Parties.
- 5.5. Assignment. Neither Party may assign any of its rights or obligations under this BAA without the prior written consent of the other Party.
- 5.6. Notice. Any notices required under this BAA shall be deemed effective on the third business day following transmission via 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.

COVERED ENTITY

**AMERICAN ACADEMY OF SLEEP
MEDICINE**

By:_____

By:_____

Print Name:_____

Name:_____

Title:_____

Title:_____

Date:_____

Address:_____

City, State, Zip:_____

Date:_____