

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“**BAA**”) is an agreement between AIRS Medical USA, Inc. (“**AIRS**” or “Business Associate”) and Customer (“Covered Entity”), and is an integral part of and subject to the terms and conditions of the Limited Evaluation Agreement or the Subscription Agreement, as applicable (each individually, the “Agreement”), governing the use of the AIRS Evaluation Product or the AIRS Service, respectively. Covered Entity and Business Associate may be referred to in this BAA individually as a “Party” or collectively as “Parties.”

This BAA shall be effective as of the date of Customer’s accepting this Agreement (the “**BAA Effective Date**”).

Capitalized terms used but not defined in this BAA shall have the meaning given to them in the Limited Evaluation Agreement/Subscription Agreement, or in HIPAA Rules (as defined below).

1. DEFINITIONS

- 1.1. “**Breach**” shall have the meaning given to such term in 45 CFR §164.402.
- 1.2. “**Electronic Protected Health Information**” or “**Electronic PHI**” shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to, 45 CFR § 160.103, as applied to the information that Business Associate creates, receives, maintains or transmits from or on behalf of Covered Entity.
- 1.3. “**HIPAA**” means the Administrative Simplification Subtitle of the Health Insurance Portability and Accountability Act of 1996, as amended by Subtitle D of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, and their implementing regulations. “**PHI**” means “protected health information” as defined in 45 C.F.R. § 160.103 that is received, maintained or transmitted by Business Associate from or on behalf of Covered Entity and that is in the AIRS Account.
- 1.4. “**Security Incident**” shall have the meaning given to such term in 45 CFR § 164.304.
- 1.5. “**Unsecured PHI**” shall have the same meaning given to such term under 45 C.F.R. § 164.402, and guidance promulgated thereunder.

2. PERMITTED AND REQUIRED USES AND DISCLOSURES

- 2.1. Except as otherwise limited in this BAA, Business Associate may use or disclose PHI for or on behalf of Covered Entity as reasonably necessary (a) to provide the AIRS Service to Covered Entity, and (b) to undertake other activities permitted or required by this BAA or applicable law.
- 2.2. Except as otherwise limited in this BAA, Business Associate may use or disclose PHI as necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate. Any disclosures under this section will be made only if Business Associate obtains reasonable assurances from the recipient of the PHI that (a) the recipient will hold the PHI confidentially and will use or disclose the PHI only as required by law or for the purpose for which it was disclosed to the recipient, and (b) the recipient will notify Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached. Business Associate may use PHI to report violations of law to appropriate federal and state authorities, consistent with 45 CFR § 164.502(j)(1).
- 2.3. Except as otherwise limited in this BAA, Business Associate may de-identify PHI in accordance with the standards set forth in 45 § CFR 164.514(b) and may use or disclose such de-identified data for the provision, development, and improvement of Business Associate’s products and services.

3. OBLIGATIONS OF BUSINESS ASSOCIATE

- 3.1. Business Associate will use or disclose PHI only as permitted by this BAA or as required by law, provided that any such use or disclosure would not violate HIPAA if done by a Covered Entity, unless permitted under HIPAA for a Business Associate.
- 3.2. Business Associate will use reasonable and appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by this BAA, consistent with the requirements of Subpart C of 45 C.F.R. Part 164 (with respect to Electronic PHI) as determined by AIRS and as reflected in the Limited Evaluation/Subscription Agreement.

- 3.3. Business Associate will report to Covered Entity any use or disclosure of PHI not permitted or required by this BAA of which AIRS becomes aware.
- 3.4. Business Associate will report to Covered Entity on no less than a quarterly basis any Security Incidents involving PHI of which AIRS becomes aware.
- 3.5. Business Associate will report to Covered Entity any Breach of Covered Entity's Unsecured PHI that AIRS may discover to the extent required by 45 C.F.R. § 164.410. Business Associate will make such report without unreasonable delay, and in no case later than five (5) calendar days after discovery of such Breach.
- 3.6. Business Associate will ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate agree to restrictions and conditions at least as stringent as those found in this BAA, and agree to implement reasonable and appropriate safeguards to protect PHI.
- 3.7. The parties do not intend for Business Associate to maintain any PHI in a Designated Record Set for Covered Entity. To the extent Business Associate maintains PHI in a Designated Record Set, Business Associate will make such information available to Covered Entity for Covered Entity to comply with 45 C.F.R. § 164.524.
- 3.8. The parties do not intend for Business Associate to disclose PHI to an Individual. If upon request by Covered Entity, Business Associate discloses PHI to an Individual, Business Associate shall document such disclosures of PHI and information related to such disclosures as would be required or Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.
- 3.9. Business Associate will make available to Covered Entity the information required to provide an accounting of disclosures in accordance with 45 C.F.R. § 164.528 of which AIRS is aware, if requested by Covered Entity. If an Individual makes a request for an accounting of disclosures of PHI pursuant to 45 CFR § 164.528 directly to Business Associate, or inquiries about his or her right to an accounting of disclosures of PHI, Business Associate shall either forward such request to Covered Entity or direct the Individual to Covered Entity.
- 3.10. Business Associate will make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of HSS for purposes of determining Covered Entity's compliance with HIPAA. Nothing in this section will waive any applicable privilege or protection, including with respect to trade secrets and confidential commercial information.
- 3.11. Business Associate will store all PHI on servers located within the United States.

4. OBLIGATIONS OF COVERED ENTITY

- 4.1. Covered Entity is responsible for implementing appropriate privacy and security safeguards in order to protect Covered Entity's PHI in compliance with all applicable law, to include HIPAA, and this BAA. Without limitation, Covered Entity will (a) utilize the highest level of audit logging in connection with Covered Entity's use of the AIRS Service, and (b) maintain the maximum retention of logs in connection with Covered Entity's use of the AIRS Service.
- 4.2. Covered Entity warrants that it has obtained any necessary authorizations, consents, and other permissions that may be required under applicable law prior to placing PHI on the AIRS Server. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.
- 4.3. Covered Entity will not agree to any restriction requests or place any restrictions in any notice of privacy practices that would cause Business Associate to violate this BAA or any applicable law. Covered Entity shall notify Business Associate of any changes in its notice of privacy practices to the extent that such limitation may affect Business Associate's use or disclosure of PHI. Covered Entity shall provide such notice no later than fifteen (15) days prior to the effective date of the limitation.
- 4.4. Covered Entity will not request or cause Business Associate to make a use or disclosure of PHI in a manner that does not comply with HIPAA, this BAA, or applicable law.

5. TERM AND TERMINATION

- 5.1. The term of this BAA will commence on the BAA Effective Date and will remain in effect with respect to the AIRS Account until the earlier of (a) the termination of the Limited Evaluation/Subscription Agreement, or (b) termination of this BAA by either party as set forth in Section 5.2 below.

- 5.2. A Party has the right to terminate this BAA if the other Party has breached a material term of this BAA and such other Party has failed to cure that material breach within 30 days after receipt of written notice thereof. A material breach of this BAA will be treated as a material breach of the Agreement.
- 5.3. Upon termination of this BAA, upon Covered Entity's request and only as commercially reasonable, Business Associate will return or destroy all PHI in any form that Business Associate maintains on behalf of the Covered Entity and retain no copies of such PHI. If such return or destruction is not feasible, Business Associate shall (i) extend the protections of this BAA to such PHI; and (ii) limit further uses and disclosures of such PHI to those purposes that make the return or destruction of the information infeasible, for as long as Business Associate is required to maintain such PHI. The Parties agree and acknowledge that it will be infeasible for Business Associate to destroy PHI that is stored on encrypted back-up medium that are stored in a secure location.
- 5.4. In the event of any conflict between the Limited Evaluation/Subscription Agreement and this BAA, the terms of this BAA will prevail.
- 5.5. Nothing in this BAA is intended to make either party an agent of the other. Nothing in this BAA is intended to confer upon Covered Entity the right or authority to control Business Associate's conduct in the course of Business Associate complying with the Limited Evaluation/Subscription Agreement and BAA.
- 5.6. Covered Entity agrees that the terms of this BAA are not publicly known and constitute AIRS Confidential Information as defined in the Limited Evaluation/Subscription Agreement.
- 5.7. Except as amended by this BAA, the Limited Evaluation/Subscription Agreement will remain in full force and effect. This BAA, together with the Limited Evaluation/Subscription Agreement as amended by this BAA: (a) is intended by the parties as a final, complete and exclusive expression of the terms of their agreement; and (b) supersedes all prior agreements and understandings (whether oral or written) between the Parties with respect to the subject matter hereof.
- 5.8. From time to time, Business Associate may modify the terms of this BAA; no modification or amendment of any portion of this BAA will be effective unless in writing and accepted by Covered Entity and by Business Associate, which acceptance may be made electronically through the AIRS Service or through other electronic means made available by Business Associate for such purpose.