

## **BUSINESS ASSOCIATE AGREEMENT AND DATA USE AGREEMENT**

THIS BUSINESS ASSOCIATE AGREEMENT AND DATA USE AGREEMENT (this “BAA/DUA”) is entered into on the dates set forth on the signature page below and made effective on \_\_\_\_\_, (the “Effective Date”), by and between the American Psychiatric Association, a District of Columbia nonprofit corporation with its principal place of business at 800 Maine Ave SW, Suite 900, Washington DC 20024 (“APA”); and \_\_\_\_\_, with its principal place of business at \_\_\_\_\_, (“Participant”) a clinician or clinician group representing its individual with authority to elect on their behalf to participate in the Registry (as defined below) and be bound by the terms of the Participation Agreement (as defined herein). APA and Participant are each a “Party” to this BAA/DUA and are referred to collectively as the “Parties.”

### **RECITALS**

APA and Participant are parties to that certain Participation Agreement, dated as of \_\_\_\_\_ (“Participation Agreement”), setting forth the terms of Participant’s participation in the clinical data registry developed by APA (“Registry”);

The Participation Agreement permits and provides for Participant, acting as a Covered Entity, to submit data to the Registry, and for APA, acting as a Business Associate, to conduct data analyses that relate to the Participant’s Health Care Operations, including but not limited to Data Aggregation, quality assessment and improvement, and peer review functions;

The Participation Agreement may from time to time require the Registry’s receipt, Use, and/or Disclosure of Protected Health Information (“PHI”) from Participant;

The Participation Agreement may from time to time require the Disclosure of PHI by Participant to the Registry in the form of a Limited Data Set (“Limited Data Set Information”) for APA to provide services to Participant related to its Health Care Operations and for Research purposes; and

The Parties desire to allocate responsibility for the Use and Disclosure of PHI, including Limited Data Set Information, and to comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”), as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public law 111-5 (“HITECH Act”) and the regulations promulgated thereunder, codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and Security Rules) (collectively referred to herein as the “HIPAA Regulations”);

NOW THEREFORE, in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the Parties agree as follows:

### **SECTION 1**

## DEFINITIONS

Capitalized terms used, but not otherwise defined, in this BAA/DUA will have the meaning ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this BAA/DUA will refer solely to PHI transmitted from or on behalf of Participant to APA or a Subcontractor of APA, or created by APA or its Subcontractor on behalf of Participant. PHI will include PHI in electronic form (“Electronic PHI”) unless specifically stated otherwise. Limited Data Set Information will have the meaning ascribed to “Limited Data Sets” in the HIPAA Regulations, but for the purposes of this BAA/DUA will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to APA or a Subcontractor of APA, or created by APA or its Subcontractor on behalf of Participant. “Subcontractor” shall have the meaning ascribed to it by the HIPAA Regulations, and shall include any agent or other person who acts on behalf of an entity, provided that APA is not acting as an agent of Participant in its role as an independent contractor herein. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

## **SECTION 2** EFFECT AND INTERPRETATION

The provisions of this BAA/DUA shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this BAA/DUA concerning the Use or Disclosure of PHI, the terms of this BAA/DUA will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this BAA/DUA are intended in their totality to implement the HIPAA Regulations as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this BAA/DUA only to the extent necessary to effectuate the provisions set forth herein.

## **SECTION 3** GENERAL OBLIGATIONS OF APA

### Section 3.1. Business Associate Obligations.

The obligations set out in this Subsection 3.1 apply with respect to APA’s Use or Disclosure of PHI, other than Limited Data Set Information.

(a) APA agrees not to Use or Disclose PHI other than as permitted or required by this BAA/DUA or as Required By Law and agrees to maintain the security and privacy of all PHI in a manner consistent with all applicable laws; provided that Participant will inform APA of any specific state laws that it believes are applicable to PHI submitted by Participant and would require APA to take compliance steps beyond those required under the HIPAA regulations.

(b) APA agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI, to prevent Use or Disclosure of PHI other

than as provided for by this BAA/DUA. Without limiting the generality of the foregoing, APA further agrees to:

(i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.308, 164.310, and 164.312;

(ii) ensure that any Subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI; and

(iii) report promptly, but in no case later than five (5) business days after Discovery, to the Participant any Security Incident or Breach of Unsecured PHI that is known to or reasonably should be known to APA and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach of Unsecured PHI; provided however, that the Parties acknowledge and agree that this Section b(iii) constitutes notice by APA to Participant of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, Use or Disclosure of PHI.

(c) APA agrees to report promptly, but in no case later than five (5) business days after Discovery (as defined by 45 CFR 164.404(a)), to Participant any Use or Disclosure of PHI which is not authorized by this BAA/DUA of which APA becomes aware.

(d) APA agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of APA, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this BAA/DUA to APA. For the purposes of this BAA/DUA, all PHI provided at APA's direction to a Subcontractor of APA will be deemed to have been provided to APA.

(e) If PHI provided to APA, or to which APA otherwise has access, constitutes a Designated Record Set, APA agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to Protected Health Information. In the event an Individual contacts APA or its Subcontractor directly about gaining access to his or her PHI, APA will not provide such access but rather will forward such request to Participant within three (3) business days of such contact, unless otherwise Required By Law.

(f) If PHI provided to APA, or to which APA otherwise has access, constitutes a Designated Record Set, APA agrees to make timely amendment(s) to such PHI as Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts APA or its Subcontractor directly about making amendments to his or her PHI, APA will not make such amendments, but rather will promptly forward such request to

Participant, unless otherwise Required By Law.

(g) APA agrees to make internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary's determining compliance with the HIPAA Regulations.

(h) APA agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, APA agrees to provide promptly to Participant or an Individual, upon Participant's reasonable request, information collected in accordance with this Subsection 3.1(h) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Subsection 3.1(h) will not apply with respect to Disclosures made to carry out Participant's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA Regulations, provided that this exception shall not apply to Disclosures of PHI through an electronic health record.

(i) APA shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of Protected Health Information by APA that are known to APA.

### Section 3.2. Limited Data Set Recipient Obligations.

The obligations set out in this Subsection 3.2 apply only with respect to APA's Use or Disclosure of Limited Data Set Information.

(a) APA agrees to not Use or further Disclose Limited Data Set Information other than as permitted by this BAA/DUA, or as otherwise Required By Law.

(b) APA agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by this BAA/DUA. Without limiting the generality of the foregoing, APA further agrees to:

(i) ensure that any Subcontractor, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information that are substantially similar to the terms of this BAA/DUA; and

(ii) report promptly, but in no case later than five (5) business days after Discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which APA becomes aware.

(c) APA will report promptly, but in no case later than five (5) business days after Discovery, to Participant any Use or Disclosure of the Limited Data Set Information not permitted by this BAA/DUA of which APA becomes aware.

(d) APA will not attempt to identify the Individuals to whom the Limited Data Set

Information pertains, or attempt to contact such Individuals, provided that this restriction will not be interpreted to prevent APA from conducting such activities under the Business Associate provisions of this BAA/DUA. Under no circumstances will APA attempt to contact Individuals except with Participant's and/or patient's prior written consent.

(e) APA agrees to require that any Subcontractor to whom it, directly or indirectly, provides Limited Data Set Information will agree in writing to comply with the same restrictions and conditions that apply through this Subsection 3.2 to APA.

(f) APA agrees to enter into a written data use agreement with each third party to which it Discloses Limited Data Set Information that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

#### **SECTION 4** **PERMITTED USES AND DISCLOSURES BY APA**

(a) General Business Associate Use and Disclosure Provisions.

Except as otherwise limited in this BAA/DUA, APA may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant's participation in Registry, consistent with the Participation Agreement, and provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, APA will be acting as an independent contractor and not as an employee or agent of Participant. APA shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

(b) Specific Business Associate Use and Disclosure Provisions.

The permitted Uses and Disclosures set out in this Subsection 4(b) apply only with respect to APA's Use or Disclosure of PHI other than Limited Data Set Information.

(i) Except as otherwise limited in this BAA/DUA or the Participation Agreement, APA may Use PHI for the proper management and administration of APA or to carry out the legal responsibilities of APA.

(ii) Except as otherwise limited in this BAA/DUA or the Participation Agreement, APA may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or APA otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify APA of any instances of which the person is aware that the Confidentiality of the PHI has been Breached.

(iii) Except as otherwise limited in this BAA/DUA or the Participation Agreement, APA may Use and Disclose PHI to provide Data Aggregation

services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(iv) APA may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. APA may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this BAA/DUA; provided that such Use or Disclosure is consistent with the Participation Agreement and applicable law.

(v) APA may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).

(c) Minimum Necessary Requirement

The Parties agree that the permissible Uses and Disclosures of Protected Health Information set forth in the Participation Agreement and this BAA/DUA are consistent with Participant's minimum necessary policies and procedures.

(d) Uses and Disclosures of Limited Data Sets.

Notwithstanding Subsection 4(b) above, APA may, consistent with this BAA/DUA, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party for Research, Public Health, or Health Care Operations in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Participant's participation in Registry or for APA's Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term Health Care Operations as used herein includes Data Aggregation.

## **SECTION 5**

### **GENERAL OBLIGATIONS OF PARTICIPANT**

(a) Participant's Notice of Privacy Practices, Permissions, and Restrictions.

(i) Participant acknowledges and agrees that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide APA with a copy of its Notice of Privacy Practices upon request.

(ii) Participant will provide APA with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect APA's permitted or required Uses and Disclosures.

(iii) Participant will ensure on a continuing basis that all Disclosures of PHI made to APA are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual's PHI to APA

impermissible. Participant will notify APA of any specific or general restrictions on the Use or Disclosure of PHI submitted to APA that Participant has agreed to in accordance with 45 CFR 164.522, if such restrictions affect APA's permitted or required Uses or Disclosures.

(b) Permissible Requests by Participant. Participant will not ask APA to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this BAA/DUA, request that APA Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of APA, as provided for in 45 CFR 164.504(e)(2).

## **SECTION 6**

### **TERM AND TERMINATION**

(a) Term. This BAA/DUA will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this BAA/DUA is terminated sooner in accordance with either Subsection (b) or (c) of this Section; or (ii) the Participation Agreement is amended by written BAA/DUA of the Parties in a manner that the Parties mutually agree renders the provisions of this BAA/DUA unnecessary.

(b) Termination for Material Breach. Either Party may terminate this BAA/DUA based upon a material breach of this BAA/DUA by the other Party, provided that the non-breaching Party gives the breaching Party thirty (30) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this BAA/DUA immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this BAA/DUA immediately and without any notice.

(c) Termination Permitted Due to Change in Law. Either Party may terminate this BAA/DUA as permitted in accordance with Section 8(b) of this BAA/DUA upon a change in an applicable law that causes performance in compliance with this BAA/DUA to violate the law. Except as otherwise specified herein, this BAA/DUA shall terminate immediately upon the termination of the Participation Agreement.

(d) Effect of Termination.

(i) Except as provided in paragraph (ii) of this Subsection and except with respect to Limited Data Set Information, upon termination of this BAA/DUA for any reason, APA will return or destroy all PHI received from Participant, or created or received by APA on behalf of Participant. APA will retain no copies of the PHI, except as provided in paragraph (ii) of this Subsection or to the extent that the PHI constitutes Limited Data Set Information.

(ii) In the event that APA reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in the Registry or for any other reason, APA will not return or destroy the PHI, may retain copies of the PHI to

the extent it has been entered into the Registry, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, APA will extend the protections of this BAA/DUA to such PHI and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as APA maintains such PHI.

(iii) The Parties acknowledge and agree that the provision of any PHI to APA in accordance with the Participation Agreement is conditioned upon this BAA/DUA being in full force and effect. Therefore, upon termination of this BAA/DUA, the Parties agree that Participant will refrain from submitting PHI to APA, and APA will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this BAA/DUA, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.

(iv) The obligations of this Subsection 6(d) will survive any expiration or termination of this BAA/DUA.

## **SECTION 7**

### **INDEMNIFICATION; BREACH NOTIFICATION**

(a) Indemnification. The Parties shall indemnify and hold harmless one another from a breach of their obligations under this BAA/DUA to the extent provided in, and subject to the limitations in Sections 8 and 9 of, the Participation Agreement. The Parties' obligations under this Section 7 regarding indemnification will survive any expiration or termination of this BAA/DUA.

(b) Breach Notification. Participant and APA agree that if either fails to adhere to any of the provisions set forth in this BAA/DUA or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the Party or Parties responsible for the Breach agree to pay all (or their proportionate share of) costs associated with any notification to affected individuals that is Required By Law, and the Party or Parties responsible will also pay any and all (or their proportionate share of) fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the Parties, if APA notifies Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with Breach Notification requirements set forth in the HIPAA Regulations. Such notification shall not identify APA unless agreed upon by APA in writing.

## **SECTION 8**

## MISCELLANEOUS

(a) Regulatory References. A reference in this BAA/DUA to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.

(b) Amendment. This BAA/DUA may not be amended except by the mutual written consent of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this BAA/DUA from time to time if necessary for Participant and/or APA to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this BAA/DUA, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of this BAA/DUA in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this BAA/DUA, the Parties agree to negotiate in good faith to amend this BAA/DUA so as to comply with such law or regulation and to preserve the viability of this BAA/DUA. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this BAA/DUA without penalty.

(c) Assignment. Neither this BAA/DUA nor either Parties' rights and obligations in this BAA/DUA may be assigned to a third party without the prior written consent of the non-assigning Party.

(d) Interpretation. Any ambiguity in this BAA/DUA will be resolved in favor of a meaning that permits Participant and APA to comply with the HIPAA Regulations or applicable state patient privacy laws or regulations. Where provisions of this BAA/DUA are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this BAA/DUA will control.

(e) No Third Party Beneficiaries. APA and Participant agree that Individuals whose PHI is Used or Disclosed to APA or its Subcontractors under this BAA/DUA are not third party beneficiaries of this BAA/DUA or the Participation Agreement.

(f) Waiver. No provision of this BAA/DUA may be waived except by a notice in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

(g) Correspondence. The Parties will send any reports or notices required under this BAA/DUA to the addresses set forth in the notice provision of the Participation Agreement.

**[Remainder of page intentionally left blank. Signature page to follow.]**

IN WITNESS WHEREOF, the Parties hereto have entered into this BAA/DUA on the dates set forth below, so that it may take effect as of the Effective Date.

**AMERICAN PSYCHIATRIC  
ASSOCIATION**

By: \_\_\_\_\_

Print Name: Kevin Madden

Title: Chief Financial Officer

**PARTICIPANT**

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_