

**APA REGISTRY**  
**PARTICIPATION AGREEMENT**

THIS AGREEMENT is entered into and made effective \_\_\_\_\_, (“Effective Date”), by and between (a) 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 (b) \_\_\_\_\_, (“Participant”), a clinician or clinician practice group representing its individual clinicians with authority to elect on their behalf to participate in APA’s Registry (as defined below) and be bound by the terms of this Agreement. APA and Participant are each a “Party” to this Participation Agreement and are referred to collectively herein as the “Parties.”

WHEREAS, APA has developed and owns certain computerized databases containing information relating to patient treatment and the practice of medicine, and third parties submit data to these databases pursuant to APA rules (said databases collectively referred to herein as the “Registry”); and

WHEREAS, Participant has expressed an interest in participating in the Registry in accordance with APA requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the Parties hereto agree as follows:

1. Participation in the Registry.

1.1 Participant agrees to participate in the Registry by transmitting data through a web-based portal or other means designated by APA, either directly or via a third-party vendor designated by Participant (a “Vendor”) for the collection and submission of data pertaining to the practice of psychiatric procedures and clinical services. Participant agrees to comply with the Terms and Conditions of Software Use for the Registry software and platform which are made available to Participant through the Registry platform.

1.2 Participant will participate in the data harvests conducted by the Registry by submitting Participant’s data to APA through the web-based portal, and otherwise complying with the rules and harvest schedules reasonably established by APA in connection therewith.

1.2.1 Participant hereby warrants, to the best of its knowledge, that all data submitted for inclusion in the Registry will be accurate and complete, and acknowledges that such data may be subject to independent audit in accordance with terms and conditions mutually agreed upon by the Parties. Participant will use its best efforts to address any data or related deficiencies identified by APA, and agrees to cooperate with and assist APA and its designees in connection with the performance of any independent audit of Participant’s data submissions or data submission process.

1.2.2 Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the Registry.

1.2.3 Participant agrees to assist and cooperate with APA in its efforts to conduct the Registry.

1.2.4 If applicable, Participant takes full responsibility for the acts and omissions of any Vendor it uses. For purposes of this Agreement, any submission of data by Participant through its Vendor shall be treated as if such data were submitted directly by Participant. The Vendor must be party to a business associate agreement with Participant which complies with the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA Regulations”) in order to act on the Participant’s behalf, and Participant acknowledges that the Vendor will not be authorized to participate in the Registry on Participant’s behalf unless such agreement remains in effect.

1.2.5 Participant represents and warrants that it has full authority to enter into this Agreement (and the BAA/DUA attached as Appendix C and more fully described in Section 5 herein) on behalf of the relevant clinicians and to bind those clinicians to the terms and conditions of this Agreement and such clinicians have agreed to be so bound. This paragraph holds true for any clinician added by Participant to the Registry subsequent to Participant signing this Agreement.

1.2.6 Whether submitting directly or via Participant’s Vendor, Participant represents and warrants that it has full legal rights and authority to submit the data to the Registry, including PHI and clinician-identifying information, and has obtained all necessary patient or clinician authorization, consent, or permission required by applicable law for the uses of the data described in this Agreement.

1.3 Participant agrees and acknowledges that its (or Vendor’s) failure to submit data to the Registry, or its (or Vendor’s) submission of data to the Registry that does not comply with APA requirements, may result in Participant’s failure to receive one or more reports generated by the Registry (see Section 2). Participant agrees to provide written notice to APA if at any time it stops submitting data to the Registry for a period of thirty (30) days or more for any reason.

1.4 Participant shall maintain the security and confidentiality of all passwords and other Registry-related credentials for its users, including by prohibiting sharing of accounts and immediately terminating access for any individual user who is no longer employed by Participant. Participant shall not allow any third party to access the Registry except its authorized users.

1.5 Participant agrees and acknowledges that the data captured by the Registry will include certain entity and clinician-identifying information (which shall be encrypted during transfer and at rest in the Registry software system). Participant agrees that it is Participant’s responsibility to obtain any permissions required in order to submit such data for inclusion in the Registry, and specifically agrees to indemnify, defend, and hold harmless APA from and against all claims and liabilities associated therewith to the extent permitted by applicable law.

2. Registry Reports. Provided that Participant participates in the Registry in accordance with APA requirements, Participant will be entitled to receive electronic access to APA data entry and review forms; reports and graphical dashboards; complimentary annual standard Registry reports, each of which will include both aggregated data from the Registry and Participant-specific information; and such other reports as APA or its independent service providers may prepare for Participants. All such reports shall be structured to reflect data of the Participant, as directed by Participant in a written request. Additional reports may be created for Participant in consideration of the fees required by APA to provide them. The aggregated data included in any and all reports provided hereunder constitute “APA Intellectual Property” (as defined herein) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in Section 6.4 of this Agreement.

3. Participant Ad Hoc Queries. Participant may submit to APA for analysis such requests for ad hoc queries (requiring access to and analysis of aggregate data from the Registry) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by APA, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken to respond thereto. In its response to each of Participant’s ad hoc queries, APA shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries and other pertinent factors; provided, however, that APA may condition its approval of a request for an ad hoc query upon Participant’s agreement to pay the fees required by the APA and any other service providers in order to appropriately address Participant’s ad hoc query. As a part of its efforts to promote the use of the Registry as a tool for the development of beneficial scientific information, APA will provide reasonable assistance to Participant in refining Participant’s requests for ad hoc queries so as to enhance their potential for approval in light of the pertinent factors noted above.

4. Fees and Membership Requirements (Appendix B). The Registry fees are set forth in Appendix B, which is attached hereto and incorporated herein by reference. Unless otherwise stated, all fees are exclusive of taxes, levies, duties or similar governmental assessments of any nature. Participant is responsible for paying all such taxes and assessments associated with any fee paid hereunder. If any amount owing by Participant is sixty (60) or more days overdue, APA may, without limiting other rights and remedies, suspend Participant’s use or access to the Registry until such amounts are paid in full. The American Board of Psychiatry and Neurology (“ABPN”) has provided a monetary grant to partially support the development of the Registry and ensure the opportunity for participation in the Registry by ABPN diplomates.

5. Confidentiality. The Parties understand that APA will need to be able to use and disclose confidential data for the purposes set forth in this Agreement. Such use and disclosure will include data aggregation and de-identification services. APA acknowledges that the data submitted to the Registry by Participant are deemed confidential. Accordingly, APA agrees and acknowledges that it will treat, and require any subcontractors with access to such data to treat, such information as confidential. The Parties hereby agree to comply with all applicable statutes and regulations, under federal and state laws, including but not limited to the HIPAA Regulations and any other applicable statutes or regulations concerning patient privacy and data security. To that end, it is agreed and acknowledged that the Parties are executing the Business Associate Agreement and Data Use Agreement (“BAA/DUA”) attached hereto as Appendix C in conjunction with their execution of this Agreement, which is incorporated herein by reference and made part of this Agreement.

## 6. Intellectual Property.

6.1 It is agreed and acknowledged that all data submitted for inclusion in the Registry by or on behalf of Participant are and shall remain Participant's proprietary information, and may be used by APA and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Participant with respect thereto (*e.g.*, in connection with data collection efforts of geographically based groups of clinicians).

6.2 Participant hereby agrees that all data submitted by or on behalf of Participant to APA or APA's designee for purposes of inclusion in the Registry may be used by APA as a part of the Registry and any subset thereof that APA may choose to create and use as it sees fit for the purposes of promoting Participant's and other Registry participants' health care operations, for medical research (as defined by the HIPAA Regulations) by APA and others authorized by APA, and the other interests of the Registry (including, without limitation, publication of such data); provided, however, that no such data shall be used and disclosed in such a way as to identify Participant or any individual clinician or clinician group, unless and until Participant advises APA in writing that it has authorized and/or secured appropriate consent for such disclosure. APA will not share Protected Health Information with third parties except as otherwise authorized under this Agreement, the BAA/DUA in Appendix C, and the HIPAA Regulations.

6.3 Participant acknowledges that APA is and shall be deemed the owner of all rights to the Registry including but not limited to the aggregate data contained therein and subsets thereof; all data fields, data elements, datasets, databases, and data dictionaries developed by and for the Registry; any and all reports based on the Registry data, and all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts); and all trademarks, trade secrets and all other intellectual property arising from or reflected in the Registry, with the exception of Participant's data (collectively, "APA Intellectual Property").

6.4 Participant may not use APA Intellectual Property without first obtaining the express written consent of APA, provided that Participant may use aggregated data from the Registry that have been included in APA reports to Participant or previously released to the public by APA (*e.g.*, in published reports and slide sets) without first obtaining such written consent so long as Participant does not make any statements about such data that are false or misleading.

6.5 Neither Party shall use the name, trademark, or logo of the other Party or its employees for promotional purposes without prior written consent of the relevant Party, except that APA may list Participant as a participating entity on its website and in other materials for noncommercial purposes.

7. CMS Quality Reporting Consents/Waivers. If the Registry or its designee is approved as Qualified Clinical Data Registry ("QCDR") or Qualified Registry for purposes of reporting physician performance measurement data under the Medicare Physician Quality Reporting System ("PQRS") and/or the Medicare Merit-Based Incentive Payment System ("MIPS"), and if Participant has submitted data to the Registry for procedures performed by clinicians who are affiliated with Participant, either as an employee, contractor, or member of Participant's

workforce; and if Participant or any such affiliated clinician wishes to participate in the PQRS and/or MIPS program through the Registry, acting either as a QCDR or a Qualified Registry, Participant hereby agrees and consents to the Registry's use of Participant's data for purposes of reporting Participant's or its affiliated clinicians' data to the Medicare program for PQRS and/or MIPS purposes. In addition, Participant and/or Participant's affiliated clinicians must execute the Registry's Consents/Waiver form as amended from time to time, as a condition of participating in the Registry's PQRS and MIPS reporting program.

8. Indemnification. APA agrees to indemnify and hold harmless Participant from and against any and all third-party claims, costs and expenses (including attorneys' fees and expenses), demands, actions and liabilities of every kind and character whatsoever (a "Claim") arising from a breach by APA of any covenant or provision under this Agreement (including the BAA/DUA), or APA's negligence, gross negligence or intentional misconduct, provided that Participant (a) promptly gives APA written notice of the Claim; (b) gives APA, at its option, sole control of the defense and settlement of the Claim (provided that APA may not settle any Claim without Participant's consent unless the settlement unconditionally releases Participant of all liability); and (c) provides to APA all reasonable assistance, at APA expense; and that the liability was not caused by the Participant's or any of its clinicians' breach of this Agreement, negligence, or intentional wrongdoing. APA's obligation to indemnify is not suspended or waived by but is reduced to the extent it is prejudiced or damaged (including loss of or restriction on insurance coverage otherwise available) by Participant's failure to do any of the foregoing in clauses (a) through (c) inclusive.

Participant agrees to indemnify, defend, and hold harmless APA and its subcontractors (if any) from and against any and all Claims arising from Participant's negligence, gross negligence or intentional misconduct, or breach of Participant's representations, warranties or obligations under this Agreement (including the BAA/DUA), absent the gross negligence or willful misconduct of APA or its subcontractors.

9. Limitation of Liability. Under no circumstances will either Party be liable to the other for any indirect or consequential damages of any kind and however caused, including lost profits or revenues arising in any way in connection with this Agreement, whether in contract, warranty, tort, negligence or under any other theory of liability and whether or not the party has been advised of the possibility of such damages. APA's total liability under this Agreement for any reason shall be limited to \$500,000.

**PARTICIPANT ACKNOWLEDGES AND AGREES THAT OTHER THAN AS EXPRESSLY PROVIDED HEREIN, THE REGISTRY IS BEING MADE AVAILABLE TO PARTICIPANT AND ITS USERS ON AN "AS IS" BASIS. APA DOES NOT WARRANT THAT THE REGISTRY WILL PERFORM UNINTERRUPTED OR ERROR FREE OR THAT IT WILL MEET PARTICIPANT'S OR ITS USERS' REQUIREMENTS AND EXPRESSLY DISCLAIMS ANY WARRANTY, WHETHER EXPRESS OR IMPLIED, NOT EXPLICITLY SET FORTH IN THIS AGREEMENT. NO ORAL OR WRITTEN INFORMATION OR ADVICE GIVEN BY APA, ITS EMPLOYEES, OR CONTRACTORS SHALL IN ANY WAY INCREASE THE WARRANTIES PROVIDED UNDER THIS AGREEMENT.**

10. Term and Termination.

10.1 Subject to the terms of Section 10.2, this Agreement shall be effective upon the Effective Date and for a period continuing until December 31<sup>st</sup> of that calendar year; **thereafter it shall be automatically renewed on an annual basis unless either Party provides the other with a written notice of termination at least sixty (60) days prior to December 31<sup>st</sup>.**

10.2 Either Party may terminate this Agreement upon sixty (60) days written notice to the other Party. This Agreement may be terminated at any time upon either Party's material breach of this Agreement and the other Party's provision of written notice thereof; provided, however, that if said breach is cured to the non-breaching Party's satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall be of no further force or effect and this Agreement shall be fully reinstated.

11. Equitable Relief. The Parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that emergency injunctive relief shall be available as a potential remedy for any such breach by either Party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching Party.

12. Independent Contractors. The relationship of the Parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, partners, or joint venturers.

13. Notices. All notices and demands of any kind or nature which either Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by United States mail, by overnight courier (e.g., Federal Express or DHL), or by email to the following addressees:

If to Participant:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Attn: \_\_\_\_\_  
Email: \_\_\_\_\_

If to APA:

American Psychiatric Association  
800 Maine Ave SW, Suite 900  
Washington DC 20024  
Attn: General Counsel  
Email: contracts@psych.org

Service of such notice or demand so made shall be deemed complete on the first business day of or after actual delivery. Either Party may, from time to time, by notice in writing served upon the other Party, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

14. Headings. The headings of the various sections hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify or place any construction upon any of the provisions of this Agreement.
15. Assignment. This Agreement may not be assigned by either Party without the prior express written approval of the other Party, except that either Party may assign this Agreement to an affiliate, successor entity, or subsidiary without the written approval of the other Party.
16. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.
17. Waiver. A waiver by either Party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.
18. Choice of Law and Forum. This Agreement shall be governed in all respects according to the laws of the District of Columbia irrespective of its choice of law rules. In addition, the Parties consent to be subject to the exclusive jurisdiction of the federal and local courts of the District of Columbia for any litigation, special proceeding, or other proceeding between the Parties that may arise out of, or be brought in connection with or by reason of, this Agreement. Each Party agrees that the provisions of this Section 18 are specifically enforceable, and that it shall pay all expenses, damages, and costs (including attorneys' fees and expense) of any other Party if it commences, prosecutes, or permits to continue any actions in any other forum.
19. Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.
20. Survival. The provisions of Sections 1.4, 5, 6, 8, 9, 11, 13, 18 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.
21. Entire Agreement. This Agreement (a) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the Parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the Party against whom enforcement is sought.

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

Is Participant a Part 2 Program, as defined by 42 C.F.R. § 2.11?    \_\_\_ YES    \_\_\_ NO

If YES, Participant must sign this Agreement in two places: (i) below Section 22, and (ii) on the final signature line. If NO, Participant should sign on the final signature line.

If Participant is a Part 2 Program, as defined by 42 C.F.R. § 2.11, the following Section 22 shall be added to this Agreement:

22. Qualified Service Organization Agreement. Participant is a Part 2 program required to comply with the regulations set forth at 42 CFR Part 2 (“Part 2”). APA is a qualified service organization providing services to Participant. To the extent that in performing its services for or on behalf of Participant, APA uses, discloses, maintains, or transmits PHI that is protected by Part 2, APA acknowledges and agrees that in receiving, storing, processing or otherwise dealing with any such patient records, it is fully bound by the regulations set forth at Part 2; and, if necessary will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the Part 2 regulations.

**PARTICIPANT**

Signed: \_\_\_\_\_

Name and Title: \_\_\_\_\_

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement, as of the date and year first written above.

**AMERICAN PSYCHIATRIC ASSOCIATION**

**PARTICIPANT**

By: \_\_\_\_\_  
Kevin Madden

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

Its: Chief Financial Officer

Its: \_\_\_\_\_

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



## **Appendix B**

### **Fees and Membership Requirements**

Registry participants should consult [www.psychiatry.org/registry](http://www.psychiatry.org/registry) for Registry fees which are subject to change by APA. Registry fees applicable for each Participants will be set forth in an annual invoice issued to that Participant.

**Appendix C**

**BUSINESS ASSOCIATE AGREEMENT  
AND DATA USE AGREEMENT**

## **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: \_\_\_\_\_