REGISTRY PARTICIPATION AGREEMENT

This Registry Participation Agreement ("Participation Agreement") is made this _____ day of __________, 20___ ("Effective Date"), between the American Academy of Neurology Institute, a 501c3, non-profit corporation, organized under the laws of Minnesota, with its principal place of business at 201 Chicago Avenue, Minneapolis, MN 55415 ("AANI"), and ___________________________ ("Participant"), located at _________________________________ (city/state). AANI and Participant are referred to in this Participation Agreement collectively as the “Parties” and individually as a “Party.”

WHEREAS, AANI has developed and owns a clinical data registry, titled “Axon Registry,” ("Registry") containing information relating to patient treatment, the Participant of the Registry, and third parties submitting data to these databases pursuant to AANI requirements; and

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

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

1. Participation in the Registry.

   a) In consideration for the rights granted to AANI as described in this Participation Agreement, Participant may enroll any of Participant’s neurologists who are members in good standing of the American Academy of Neurology ("AAN") in the Registry without charge. Participant’s enrolled members are listed in Appendix A.

   b) Participant agrees to participate in the Registry by transmitting data through a web-based portal or other means designated by AANI, either directly or via a third-party vendor (e.g., EHR vendor or other data management company) designated by Participant ("Participant’s Vendor") for the collection and submission of data pertaining to the Participant of the Registry.

   c) Participant must implement the data collection protocols provided by AANI or AANI’s technology vendor for the Registry ("AANI’s Vendor") to properly submit data to the Registry. Participant will participate in the data harvests conducted by the Registry by submitting Participant’s data to the AANI’s Vendor and otherwise complying with the requirements and harvest schedules reasonably established by AANI.

   d) Participant agrees to assist and cooperate with AANI in its efforts to conduct the Registry.
e) Participant takes full responsibility for the acts and omissions of the Participant’s Vendor in Participant’s involvement in the Registry. For purposes of this Participation Agreement, any submission of data by Participant through the Participant’s Vendor is treated as if such data were submitted directly by Participant. Participant agrees that Participant’s Vendor must enter into a business associate agreement with Participant in order to act on the Participant’s behalf. Participant acknowledges that Participant’s Vendor will not be authorized to Participate in the Registry on Participant’s behalf until such an agreement is completed. Participant will immediately notify AANI of any changes to the business associate agreement with Participant and the Participant’s Vendor.

f) Participant agrees and acknowledges that its or Participant’s Vendor’s failure to submit data to the Registry, or its or Participant’s Vendor’s submission of data to the Registry that does not comply with AANI requirements, may result in Participant’s failure to receive reports generated by the Registry as described in Section 2.

g) Participant agrees and acknowledges that the data captured by the Registry will include certain entity and physician-identifying information. Participant agrees that it is Participant’s responsibility to obtain any permissions required in order to submit such data for inclusion in the Registry.

h) Participant agrees to select a staff member to be the primary contact for the Registry.

2. AANI Reports. Provided that Participant participates in the Registry in accordance with AANI requirements, Participant will be entitled to receive electronic access to AANI data entry and review forms; the Registry dashboard; standard Registry reports as determined and distributed by AANI; and other reports as AANI or its independent service providers may prepare for Participants. Registry-generated reports may, at AANI’s discretion, be structured to reflect data of the Participant, as requested by Participant in writing to AANI. The aggregated data included in any and all reports provided constitute “AANI Intellectual Property” (as defined in this Participation Agreement) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in Section 5.d. of this Agreement or as otherwise permitted by AANI.

3. Participant Ad Hoc Queries. Participant may submit to AANI for analysis 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 AANI and any fees, procedures and other requirements as AANI may reasonably determine. AANI will give due consideration to scientific merit, the funds and other resources available to address ad hoc queries and other pertinent factors. As a part of its efforts to promote the use of the Registry as a tool for the development of beneficial clinical Participant information, AANI will provide reasonable assistance to Participant when able 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.

a) AANI acknowledges that the data submitted to the Registry by Participant are deemed confidential. Accordingly, AANI agrees and acknowledges that it will require AANI’s Vendor to treat such information as confidential. AANI agrees to comply with the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 by the United States Department of Health and Human Services, codified at 45 CFR Parts 160 and 164, 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, and any current and future regulations promulgated under either (collectively, “HIPAA Regulations”). To that end, it is agreed and acknowledged that the Parties are executing the “Business Associate Agreement and Data Use Agreement,” (“BAA/DUA”) attached as Appendix B, which is incorporated by reference and made part of this Participation Agreement.

b) Excluding the Participant’s data, which is addressed in Section 4.a., the Parties may exchange other confidential information, including software or business, financial, operational, customer, and vendor information, as disclosed by one Party to the other Party and designated by the disclosing Party as confidential or proprietary (including the terms of this Participation Agreement) (“Confidential Information”). Each Party must maintain the other Party’s Confidential Information in strict confidence and must protect such information with the same degree of care that Party exercises with its own Confidential Information, but in no event less than a reasonable degree of care. Except as provided in this Participation Agreement, a Party must not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of the other Party. Access to and use of any Confidential Information must be restricted to those representatives within a Party’s organization with a “need to know” such Confidential Information who are subject to confidentiality obligations no less stringent than those applicable to such Party under this Participation Agreement. AANI may share Participant’s Confidential Information with AANI’s Vendor on a “need to know” basis. AANI’s Vendor is subject to confidentiality obligations no less stringent than those applicable to AANI under this Participation Agreement. Notwithstanding the foregoing, Confidential Information does not include information: (i) already known to or otherwise in the possession of a Party at the time of receipt from the other Party; (ii) publicly available or otherwise in the public domain prior to disclosure by a Party; (iii) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (iv) developed by a Party independent of any disclosure hereunder, as evidenced by written records; or (v) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order must notify the other Party prior to such disclosure and must cooperate with the other Party in the event the other Party elects to legally contest, request confidential treatment or otherwise avoid such disclosure. Except as otherwise provided herein, all of a Party’s Confidential Information, and any copies or derivatives thereof, are and remain the property of such Party and must be promptly returned or destroyed at the disclosing Party’s direction.
5. **Intellectual Property.**

a) It is agreed and acknowledged that all individual data submitted for inclusion in the Registry by or on behalf of Participant are and shall remain Participant’s proprietary information. Once submitted to the Registry, the return of the Participant’s individual data, including protected health information as defined by the HIPAA Regulations (“PHI”), is infeasible, as it will have been integrated into the Registry. Participant grants to AANI a perpetual, worldwide, royalty-free license, in all forms and all media (including derivative works), to use the data submitted by Participant in any manner that is consistent with this Participation Agreement, the BAA/DUA, and the HIPAA Regulations.

b) Participant agrees that all data submitted by or on behalf of Participant to AANI or AANI’s designee for purposes of inclusion in the Registry may be used by AANI as a part of the Registry and any subset thereof that AANI 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 HIPAA regulations) by AANI and others authorized by AANI, and the other interests of the Registry (including 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 physician or physician group, unless and until Participant advises AANI in writing that it has authorized or secured appropriate consent for such disclosure. AANI will not share PHI with third-parties except as otherwise authorized under this Agreement, the BAA/DUA, and the HIPAA Regulations.

c) Participant acknowledges that AANI is and shall be deemed the owner of all rights to the Registry including the aggregate data contained in the Registry and subsets of the aggregate data, any and all reports based on the Registry data, all information derived from the Registry (including 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 (collectively, “AANI Intellectual Property”) with the exception of Participant’s individual data. AANI has full and unencumbered rights to publish, disclose, distribute, market, sell, and create derivatives of, AANI Intellectual Property in any form.

d) Participant may not use AANI Intellectual Property without first obtaining the express written consent of AANI, provided that Participant may use aggregated data from the Registry that have been included in AANI reports to Participant or previously released to the public by AANI (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 and Participant’s use complies with the AANI’s Data Use Requirements for use of such data (which AANI will provide to Participant).

e) 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 other Party, except that
AANI may list Participant as a participating entity on its website and in other materials listing its participating entities for noncommercial purposes.

6. **Representations & Warranties.**

   a) 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 physician-identifying information, and has obtained all necessary patient or physician authorization, consent, or permission required by applicable law for the uses of the data described in this Participation Agreement.

   b) Participant 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 of the data to be conducted by a vendor selected by the AANI, 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 AANI, AANI’s Vendor or other designated vendor, and agrees to cooperate with and assist AANI and its designees in connection with the performance of any independent audit. AANI may reject or remove from the Registry any Participant’s data it determines is deficient in any manner.

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

7. **Indemnification; Limitation of Liability.**

   a) AANI agrees to indemnify, defend, 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 arising or resulting in any way from AANI’s breach of its obligations under this Participation Agreement, absent the negligence or misconduct of Participant. All of the foregoing rights of indemnification shall apply to any expenses incurred by Participant in defending itself against claims of negligence or misconduct unless a court of competent jurisdiction concludes in a final judgment that Participant has committed negligence or misconduct.

   b) Participant agrees to indemnify, defend, and hold harmless AANI, AAN, and AANI’s Vendor, from and against any and all third-party claims (including claims made by Participant’s Vendor or Participant’s physicians), costs and expenses (including attorneys’ fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from Participant’s breach of its obligations, representations or warranties, under this Participation Agreement, absent the negligence or misconduct of AANI. All of the foregoing rights of indemnification shall apply to any expenses incurred by AANI, AAN or AANI’s Vendor in defending themselves, respectively, against claims of negligence or misconduct unless a court of competent
jurisdiction concludes in a final judgment that AANI, AAN, or AANI’s Vendor has committed negligence or misconduct.

c) Under no circumstances will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Participation Agreement.

8. **Insurance.** At all times during the term of this Participation Agreement and the accompanying BAA/DUA, Participant and AANI shall maintain insurance with coverage and limits reasonably sufficient to cover their respective obligations hereunder and shall provide proof of such insurance upon the other Party’s request. Participant may satisfy the foregoing requirement through an appropriate self-insurance program, but must provide proof of such insurance upon AANI’s request.

9. **Term and Termination.**

a) Subject to the terms of this Section 8, this Participation Agreement shall be effective through December 31, 2017, and shall be automatically renewed on an annual basis thereafter unless any Party provides the other with a written notice of termination on or before December 1, 2017, or December 1 of any subsequent renewal year.

b) Either Party may terminate this Participation Agreement upon sixty days written notice to the other Party, provided that any such termination by Participant must be effective at the end of the calendar quarter in which AANI receives the notice.

c) This Participation Agreement may be terminated upon any Party’s material breach of this Participation Agreement and any 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 days after the provision of such notice, said termination notice shall be of no further force or effect and this Participation Agreement shall be fully reinstated.

d) AANI reserves the right to immediately terminate this Participation Agreement and Participant’s participation in the Registry if it determines that the Participant’s data submission for any two calendar quarters within a rolling twelve month calendar year is noncompliant with the Registry data quality requirements or is otherwise unacceptable for inclusion in the Registry. AANI may, in its sole discretion, provide the Participant with the opportunity to cure the inadequate data without affecting AANI’s rights to terminate this Participation Agreement under this Section 8.d. or otherwise.

10. **Warranty Disclaimer.** AANI does not represent or warrant that access to the Registry will be uninterrupted or error free or that data will not be lost, provided the AANI and AANI’s Vendor have acted in good faith and there is no willful misconduct or violation of law that resulted in such interruption, error or loss. AANI Registry data, reports, and performance
measures: 1) do not establish a standard of medical care, and have not been tested for all potential applications; 2) are not continually updated and may not reflect the most recent information; and 3) are subject to review and may be revised or rescinded at any time by the AANI. Registry data, reports, and performance measures and related data specifications do not mandate any particular course of medical care and are not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. AANI provides this information on an “as is” basis, and makes no warranty, expressed or implied, regarding the information. AANI specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. AANI assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

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 Participation Agreement, and that emergency injunctive relief shall be available as a potential remedy for any such breach by any other Party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Participation 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 Participation Agreement is that of independent contractors, and not that of principal and agent, employer and employee, or partners or joint venturers.

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

If to Participant:
____________________________________
____________________________________
____________________________________
____________________________________
Tel: ______________________________
(fax #) __________________________
Attn: ___________________________

If to AANI:
American Academy of Neurology Institute
201 Chicago Avenue
Minneapolis, MN 55415
Attn: General Counsel
Attn: Director, Quality Improvement
Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any Party hereto may, from time to time, by notice in writing served upon the other Party(ies) as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

14. **Modifications.**

   a) The Registry is a newly developed service of the AANI and, as such, may be subject to modification or adjustment by AANI. AANI may, from time-to-time, modify or amend the substantive provisions of this Participation Agreement related to the manner in which the Registry operates, so long as such modifications or amendments are of general applicability to all similarly situated participants in the Registry. Participant will be bound by any modifications or amendments to this Participation Agreement unless, within thirty days of receipt of such modification or amendment, Participant notifies AANI pursuant to Section 12 of this Participation Agreement that a specific modification or amendment is not acceptable to it, in which case, this Participation Agreement and Participant’s participation in the Registry will terminate effective at the end of the thirty day period in which AANI receives such notice. In addition, during the foregoing pre-termination period, Participant does not have the right to submit further data to the Registry, but the other provisions of this Participation Agreement will apply.

   b) In the event the Registry is subject to the jurisdiction of an Institutional Review Board (“IRB”), AANI may amend this Participation Agreement with notice to Participant to conform to the requirements of the IRB. AANI must disclose the IRB utilized for review and findings of such review to Participant upon Participant’s request.

15. **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 Participation Agreement.

16. **Assignment.** This Participation Agreement may not be assigned by any party without the prior express written approval of the other Party, except that either party may assign this Participation Agreement to an affiliate, parent organization, successor entity, or subsidiary without the written approval of the other Party.

17. **Counterparts.** This Participation 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.
18. **Waiver.** A waiver by any party to this Participation 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.

19. **Choice of Law and Forum.** All disputes regarding the meaning, effect, force or validity of this Participation Agreement shall be determined according to federal law and the law of the State of Minnesota. The Parties expressly agree that the federal and state courts located in the State of Minnesota are the most reasonable and convenient forums for resolutions of any such disputes, and designate said courts as the exclusive forums in which all such disputes shall be litigated. Accordingly, the Parties consent to the jurisdiction and venue of, and service of process by, said courts. 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 said other Party commences, prosecutes, or permits to continue any actions in any other forum.

20. **Severability.** All provisions of this Participation Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Participation Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

21. **Survival.** The provisions of Sections 1.e., 4, 5, 6, 7, 8, 11, 19 and all other terms within this Participation Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Participation Agreement.

22. **Entire Agreement.** This Participation 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.

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

AMERICAN ACADEMY OF NEUROLOGY INSTITUTE

PARTICIPANT

By: ________________________________
   Catherine M. Rydell, CAE
   Executive Director and CEO

By: ________________________________
   Printed Name: ____________________

Date: _______________________________
   Title: _____________________________

Date: _______________________________
APPENDIX A

[List of AAN members from Participant’s practice participating in the Registry]
This Business Associate Agreement and Data Use Agreement ("BAA/DUA") is made this ______ day of ___________________, 20___ ("Effective Date"), between the American Academy of Neurology Institute, a 501c3, non-profit corporation, organized under the laws of Minnesota, with its principal place of business at 201 Chicago Avenue, Minneapolis, MN 55415 ("AANI"), and ____________________________ ("Participant"), located at ________________________________ (city/state). AANI and Participant are referred to in this BAA/DUA collectively as the “Parties” and individually as a “Party.”

RECITALS

AANI and Participant are parties to that certain Participation Agreement, dated as of __________________________ ("Participation Agreement"), setting forth the terms of Participant’s participation in the Registry;

The Participation Agreement permits and provides for the Participant, acting as a Covered Entity, to submit data to the Registry, and for AANI, 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 receipt, Use, and/or Disclosure of Protected Health Information ("PHI");

The Participation Agreement may from time to time require the Disclosure of PHI in the form of a Limited Data Set ("Limited Data Set Information") for AANI 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") and the regulations promulgated thereunder by the United States Department of Health and Human Services ("HHS") codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and Security Rules) 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"), (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 AANI or a Subcontractor of AANI, or created by AANI 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 AANI or a Subcontractor of AANI, or created by AANI 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 AANI 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 45 CFR 164.504(e) and 45 CFR 164.314(a) 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 AANI

Section 3.1. Business Associate Obligations.

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

(a) AANI 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 the HIPAA Regulations.

(b) AANI 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, AANI 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 164.314(a);

(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 AANI and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach; provided however, that the Parties acknowledge and agree that this Section b(iii) constitutes notice by AANI 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) AANI agrees to report promptly, but in no case later than five (5) business days after Discovery, to Participant any Use or Disclosure of PHI which is not authorized by this BAA/DUA of which AANI becomes aware.

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

(e) If PHI provided to AANI, or to which AANI otherwise has access, constitutes a Designated Record Set, AANI 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 AANI or its Subcontractor directly about gaining access to his or her PHI, AANI 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 AANI, or to which AANI otherwise has access, constitutes a Designated Record Set, AANI 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 AANI or its Subcontractor directly about making amendments to his or her PHI, AANI will not make such amendments, but rather will promptly forward such request to Participant, unless otherwise required by law.

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

Section 3.2. Limited Data Set Recipient Obligations.

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

(a) AANI agrees to not Use or further Disclose Limited Data Set Information other than as permitted by Section 4(d) of this BAA/DUA, or as otherwise Required By Law.

(b) AANI agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by Section 4(d) of this BAA/DUA. Without limiting the generality of the foregoing, AANI further agrees to:

(i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set Information that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314(a);

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

(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 of which AANI becomes aware.

(c) AANI 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 Section 4(d) of this BAA/DUA of which AANI becomes aware.

(d) AANI 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 AANI from conducting such activities under the Business Associate provisions of this BAA/DUA. Under no circumstances will AANI attempt to contact Individuals except with Participant’s prior written consent.

(e) AANI 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 Section 3.2 to AANI.

(f) AANI 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 AANI

(a) General Business Associate Use and Disclosure Provisions. Except as otherwise limited in this BAA/DUA, AANI 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 the Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, AANI will be acting as an independent contractor and not as an employee or agent of Participant. AANI 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 AANI’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, AANI may Use PHI for the proper management and administration of AANI or to carry out the legal responsibilities of AANI.

(ii) Except as otherwise limited in this BAA/DUA or the Participation Agreement, AANI may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or AANI 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 AANI 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, AANI may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(iv) AANI 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. AANI 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) AANI 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) 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, AANI 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 the Registry or for AANI’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 AANI with a copy of its Notice of Privacy Practices upon request.

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

(iii) Participant will ensure on a continuing basis that all Disclosures of PHI made to AANI are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual’s PHI to AANI impermissible. Participant will notify AANI of any specific or general restrictions on the Use or Disclosure of PHI submitted to AANI that Participant has agreed to in accordance with 45 CFR 164.522, if such restrictions affect AANI’s permitted or required Uses or Disclosures.

(b) Permissible Requests by Participant. Participant will not ask AANI 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 AANI Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of AANI, as provided for in 45 CFR 164.504(e)(4).

(c) Breach Notification. Participant and AANI agree that if either fails to adhere to any of the provisions set forth in this BAA/DUA or the Participation Agreement, 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 AANI 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 AANI unless agreed upon by AANI in writing.
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 agreement 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, AANI will return or destroy all PHI received from Participant, or created or received by AANI on behalf of Participant. AANI 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 AANI reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in the Registry or for other reason, AANI 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, AANI 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 AANI maintains such PHI.

(iii) The Parties acknowledge and agree that the provision of any PHI to AANI 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 AANI, and AANI 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

AANI agrees to indemnify and hold harmless Participant from direct losses and damages relating to third-party claims suffered by Participant as a result of AANI’s breach of its obligations under this BAA/DUA. Participant agrees to indemnify and hold harmless AANI from direct losses and damages relating to third-party claims suffered by AANI as a result of Participant’s breach of its obligations under this BAA/DUA. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this BAA/DUA. The Parties’ obligations under this Section 7 regarding indemnification will survive any expiration or termination of this BAA/DUA.

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 agreement 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 AANI 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 AANI 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) **Third Party Beneficiaries.** AANI and Participant agree that Individuals whose PHI is Used or Disclosed to AANI 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 an agreement 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.

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 ACADEMY OF NEUROLOGY INSTITUTE**

By: ____________________________
Catherine M. Rydell, CAE
Executive Director and CEO

Date: ____________________________

**PARTICIPANT**

By: ____________________________

Printed Name:_____________________

Title:____________________________

Date:____________________________