**THE ANESTHESIA QUALITY INSTITUTE**

 **NATIONAL ANESTHESIA CLINICAL OUTCOMES REGISTRY**

**PARTICIPATION AGREEMENT**

THIS AGREEMENT is entered into effective the day of , 20\_\_, by and between (a) THE ANESTHESIA QUALITY INSTITUTE, an Illinois not-for-profit corporation with its principal place of business at 1601 American Ln, Schaumburg, IL 60173 (“AQI”); and (b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a group of anesthesiologists or healthcare facility whose principal place of business is at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Participant”).

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

WHEREAS, the successful operation of the National Anesthesia Clinical Outcomes Registry is dependent in large measure on Participants’ use of computer software that meets AQI specifications for content, functionality, and otherwise or submission of data through a web-based portal designated by AQI; and

WHEREAS, Participant has expressed an interest in participating in the AQI Registry in accordance with AQI 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 AQI National Anesthesia Clinical Outcomes Registry.

1.1 Participant agrees to participate in the AQI National Anesthesia Clinical Outcomes Registry by transmitting data pertaining to the practice of anesthesiology.

1.2 Participant will participate in the data harvests conducted by the AQI Registry by submitting Participant’s data to the AQI through the AQI’s secure portal or by direct transmission from vendor (the “Vendor”) software in use by Participant, and otherwise complying with the rules and harvest schedules reasonably established by AQI in connection therewith.

 1.2.1 Participant hereby warrants that all data submitted for inclusion in the AQI National Anesthesia Clinical Outcomes Registry will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the AQI, and agree to cooperate with and assist AQI and its designees in connection with the performance of any independent audit.

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

 1.2.3 Participant agrees to assist and cooperate with AQI in their efforts to conduct the AQI Registry.

 1.2.4 For Participant anesthesiology groups, the undersigned representative of such group represents and warrants that s/he is authorized to enter into this Agreement on behalf of the Participant anesthesiology group and that all professional members of the group and/or the duly elected or appointed decision makers for the group have consented to the submission of data to the AQI.

 1.2.5 Participant takes full responsibility for the acts and omissions of the Vendor in Participant’s participation in the Registry. For purposes of this Agreement, any submission of data by Participant through the Vendor shall be treated as if such data were submitted directly by Participant. Participant will immediately notify AQI of any changes to the agreement with Participant and the Vendor. The Vendor must also complete an Authorized Vendor Agreement with AQI in order to act on the Participant’s behalf and Participant acknowledges that Vendor will not be authorized to Participate in the Registry on Participant’s behalf until such agreement is completed.

1.3 Participant agrees and acknowledges that its (or Vendor’s) failure to submit data to the AQI Registry, or its or (Vendor’s) submission of data to the AQI Registry that does not comply with AQI requirements, may result in Participant’s failure to receive one or more reports generated by the AQI Registry (see paragraph 2).

1.4 Participant agrees and acknowledges that the data captured by the AQI Registry will include certain healthcare facility identifying information, as well as certain provider identifying information (both in an encrypted form during transfer and at rest in the AQI software system). Participant agrees that it is Participant’s responsibility to obtain any permission(s) required in order to submit such data for inclusion in the AQI Registry. AQI and Participant agree to accept liability for the acts and omissions of their own agents and employees, to the extent permitted by law

2. AQI National Anesthesia Clinical Outcomes Registry Reports. Provided that Participant participates in the AQI Registry in accordance with AQI requirements (including but not limited to Participant’s payment of all applicable fees), Participant will be entitled to receive quarterly and annual AQI Registry reports, each of which will include both aggregated data from the AQI Registry and Participant-specific information, and such other reports as AQI or its independent service providers may prepare for Participants. All such reports shall be structured to reflect data of the Anesthesiologist Participant or the Hospital Participant (if any), as directed by Participant. Additional reports may be created for Participant in consideration for the fees required by AQI in order to provide them. The aggregated data included in any and all reports provided hereunder constitute “AQI Intellectual Property” (as defined herein) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in paragraph 6.4 of this Agreement or as otherwise permitted by AQI policies and procedures .

3. Participant Ad Hoc Queries. Participant may submit to AQI for analysis such requests for ad hoc queries (requiring access to and analysis of aggregate data from the AQI Registry) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by AQI, 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, AQI 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 if adequate funding is not otherwise available, AQI may condition its approval of a request for an ad hoc query upon Participant’s agreement to pay the fees required by the AQI and any other service providers required in order to appropriately address Participant’s ad hoc query. As a part of its efforts to promote the use of the National Registry as a tool for the development of beneficial scientific information, AQI 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. Participant Fees.

4.1 Fees payable by Participant to AQI pursuant to this Agreement are as follows:

4.1.1 Participant will be required to pay a fee annually to receive AQI reports. The fee will be $1,000 per independent anesthesia provider in the group, but will be waived for providers who are members of the American Society of Anesthesiologists.

4.1.2 Such participation fees as AQI may establish for future calendar years, provided that said fees will be established by AQI prior to December 1 in each year this Agreement is in effect (payable by January 1 of the succeeding year).

4.2 Any additional report-related fees required pursuant to paragraph 2.

4.3 Any additional ad hoc query fees required pursuant to paragraph 3.

5. Confidentiality. AQI acknowledges that the data submitted to the AQI Registry by Participant are deemed confidential. Accordingly, AQI agrees and acknowledges that it will treat such information as confidential, and will require this treatment as well from any future contractor that AQI might engage to assist with management of the AQI National Anesthesia Clinical Outcomes Registry. The parties hereby agree to comply with all statutes and regulations, under federal and state laws, including but not limited to the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and any other applicable statutes or regulations concerning patient privacy and data security. To that end, it is agreed and acknowledged that they are executing the Business Associate Contract and Data Use Agreement attached hereto as Appendix I 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 AQI Registry by or on behalf of Participant are and shall remain Participant’s proprietary information, and may be used by AQI and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Participant with respect thereto.

6.2 Participant hereby agrees that all data submitted by or on behalf of Participant to AQI or AQI’s designee for purposes of inclusion in the AQI Registry may be used by AQI as a part of the AQI Registry and any subset thereof that AQI may choose to create and use as it sees fit for the purposes of promoting of Participant’s health care operations and medical research (as defined by HIPAA regulations), anesthesiologist self-assessment and the other interests of the AQI Registry (including, without limitation, publication of such data); provided, however, that no such data shall be used or disclosed in such a way as to identify Participant or institution of Participant or any individual physician or physician group, unless and until Participant advises AQI in writing that it has authorized and/or secured appropriate consent.

6.3 Participant acknowledges that AQI is and shall be deemed the owner of all rights to the AQI Registry (including the aggregate data contained therein and subsets thereof), any and all reports based thereon, all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts) and all trademarks (including, without limitation, THE ANESTHESIA QUALITY INSTUTUTE, AQI, AQI NATIONAL ANESTHESIA CLINICAL OUTCOMES REGISTRY and all variations thereon and graphic representations thereof), trade secrets and all other intellectual property arising from or reflected in the AQI Registry (collectively, “AQI Intellectual Property”) with the exception of Participant’s data.

6.4 Participant may not use AQI Intellectual Property without first obtaining the express written consent of AQI, provided that Participant may use aggregated data from the AQI Registry that have been previously included in AQI Reports to Participant or released to the public by AQI (*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 other party.

7. Limitation of Liability; Indemnification. AQI agrees to indemnify, save 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 AQI’s breach of its obligations under this Agreement, absent the gross negligence or willful misconduct of Participant. All of the foregoing rights of indemnification shall apply to any expenses incurred by Participant in defending itself against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

Participant agrees to indemnify, save and hold harmless AQI and its independent data warehouse service provider (if any) 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 Participant’s submission of data to the Registry or use of data obtained through the Registry, absent the gross negligence or willful misconduct of AQI or any independent data warehouse service provider, respectively. All of the foregoing rights of indemnification shall apply to any expenses incurred by AQI and any independent data warehouse service provider in defending themselves, respectively, against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

8. Term and Termination.

8.1 Subject to the terms of paragraph 8.2, this Agreement shall be effective through December 31, 20 , and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination on or before December 31, 20 , or December 1 of any subsequent renewal year.

8.2 This Agreement may be terminated prior to December 31, 20 (or December 31 of any subsequent renewal year) upon any party’s material breach of this 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(ies’) satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall of no further force or effect and this Agreement shall be fully reinstated.

8.3 Either party may terminate this Agreement upon sixty (60) days written notice to the other party. This Agreement may be terminated prior to December 31 of this year, (or December 31 of any subsequent renewal year) upon any party’s material breach of this 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(ies’) satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall of no further force or effect and this Agreement shall be fully reinstated.

9. 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 each party shall be entitled to emergency injunctive relief as a 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 Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party(ies).

10. 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, or partners or joint venturers.

11. Notices. All notices and demands of any kind or nature which any 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 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (fax #) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If to AQI: The Anesthesia Quality Institute

1601 American Ln

Schaumburg, IL 60173

Tel: 847-268-9226

 (fax #) 847-825-2085

Attn: Richard P. Dutton, MD

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.

12. Headings. The headings of the various paragraphs 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.

13. Assignment. This Agreement may not be assigned by any party without the prior express written approval of the other party(ies), except that either party may assign this Agreement to an affiliate, successor entity, or subsidiary without the written approval of the other party.

14. 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.

15. Waiver. A waiver by any 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.

16. Choice of Law and Forum. All disputes regarding the meaning, effect, force or validity of this Agreement shall be determined according to federal law and the law of the {insert state of practice here}. The parties expressly agree that the federal and state courts located in the {insert state of practice here}, 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 paragraph 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.

17. 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, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

18.       Survival.  The provisions of paragraph 1.4 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.

19. 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.

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

THE ANESTHESIA QUALITY PARTICIPANT

INSTITUTE

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

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

**APPENDIX I: STANDARD FORM**

**BUSINESS ASSOCIATE CONTRACT**

**AND DATA USE AGREEMENT**

THIS AGREEMENT is entered into and made effective the day of , 20\_\_\_ (the “Effective Date”), by and between (a) **THE ANESTHESIA QUALITY INSTITUTE**, a not-for-profit corporation, with its principal place of business at 1601 American Ln, Schaumburg, IL 60173(“AQI”); and (b) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a hospital or group of anesthesiologists whose principal place of business is at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Participant)

**WHEREAS**, AQI and Participant are parties to that certain Participation Agreement, dated as of , 20\_\_\_, setting forth the terms of Participant’s participation in the AQI Registry (such agreement to be referred to herein as the “Participation Agreement” and such AQI National Anesthesia Clinical Outcomes Registry as “Registry”);

**WHEREAS**, the Participation Agreement permits and provides for the conduct of data analyses that relate to the Participant’s Health Care Operations, including but not limited to Data Aggregation, quality assessment, and peer review functions;

**WHEREAS,** the Participation Agreement may from time to time require the receipt, Use, and/or Disclosure of Protected Health Information (“PHI”);

**WHEREAS,** 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 AQI to provide services to Participant related to its Health Care Operations and for Research purposes;and

**WHEREAS**, the Parties desire to amend the Participation Agreement so as 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”), as they pertain to Business Associates and Limited Data Sets;

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

1. **DEFINITIONS**

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be. Except as otherwise specified herein, the term “Agreement” refers to this Business Associate Contract and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to AQI or a Subcontractor of AQI, or created by AQI 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 Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to AQI or a Subcontractor of AQI, or created by AQI 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 AQI 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.

1. **EFFECT AND INTERPRETATION**

The provisions of this Agreement 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 Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement 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 Agreement 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 Agreement only to the extent necessary to effectuate the provisions set forth herein.

1. **GENERAL OBLIGATIONS OF AQI**

Section 3.1. Business Associate Contract Obligations.

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

* 1. AQI agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.
	2. AQI 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 Agreement. Without limiting the generality of the foregoing, AQI further agrees to:
		+ 1. 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);
			2. 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
			3. report promptly to the Participant any Security Incident or Breach of Unsecured PHI of which AQI becomes aware.
	3. AQI agrees to report promptly to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which AQI becomes aware.
	4. AQI agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of AQI, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to AQI. For the purposes of this Agreement, all PHI provided at AQI’s direction to a Subcontractor of AQI will be deemed to have been provided to AQI.
	5. If PHI provided to AQI, or to which AQI otherwise has access, constitutes a Designated Record Set, AQI 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 PHI. In the event an Individual contacts AQI or its Subcontractor directly about gaining access to his or her PHI, AQI will not provide such access but rather will forward such request to Participant within three (3) business days of such contact.
	6. If PHI provided to AQI, or to which AQI otherwise has access, constitutes a Designated Record Set, AQI 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 AQI or its Subcontractor directly about making amendments to his or her PHI, AQI will not make such amendments, but rather will forward such request to Participant within three (3) business days.
	7. AQI 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.
	8. AQI 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, AQI 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 for which an accounting is not required by 45 CFR 164.528 as amended.
	9. AQI shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of Protected Health Information by AQI that are known to AQI.

 Section 3.2. Data Use Agreement Obligations.

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

 (a) AQI agrees to not Use or further Disclose Limited Data Set Information other than as permitted by Section 4(c) of this Agreement, or as otherwise Required By Law.

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

* + - 1. 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);
			2. ensure that any Subcontractor, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information;
			3. report within 5 business days to the Participant any Security Incident or Breach of Unsecured PHI of which AQI becomes aware.

 (c) AQI will report within 5 business days to Participant any Use or Disclosure of the Limited Data Set Information not permitted by Section 4(c) of this Agreement of which AQI becomes aware.

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

 (e) AQI 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 AQI.

1. AQI agrees to enter into a written 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.
2. **PERMITTED USES AND DISCLOSURES BY AQI**
	1. General Business Associate Contract Use and Disclosure Provisions.

Except as otherwise limited in this Agreement, AQI 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 AQI 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, AQI will be acting as an independent contractor and not as an employee or agent of Participant. AQI shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

* 1. Specific Business Associate Contract Use and Disclosure Provisions.

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

* + - 1. Except as otherwise limited in this Agreement or the Participation Agreement, AQI may use PHI for the proper management and administration of AQI or to carry out the legal responsibilities of AQI.
			2. Except as otherwise limited in this Agreement or the Participation Agreement, AQI may *Disclose* PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or AQI 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 AQI of any instances of which the person is aware that the Confidentiality of the PHI has been breached.
			3. Except as otherwise limited in this Agreement or the Participation Agreement, AQI may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).
			4. AQI 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. AQI 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 Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement.
			5. AQI 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) Uses and Disclosures Under Data Use Agreement Provisions.

Notwithstanding Subsection 4(b) above, AQI may, consistent with this Agreement, 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 AQI Registry or for AQI’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.

1. **GENERAL OBLIGATIONS OF PARTICIPANT**
	1. Participant’s Notice of Privacy Practices, Permissions, and Restrictions.
		* 1. Participant represents and warrants 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 AQI with a copy of its Notice of Privacy Practices upon request.
			2. Participant will provide AQI with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect AQI’s permitted or required Uses and Disclosures.
			3. Participant will ensure on a continuing basis that all Disclosures of PHI made to AQI are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual’s PHI to AQI impermissible. Participant will notify AQI of any specific or general restrictions on the Use or Disclosure of PHI submitted to AQI that Participant has agreed to in accordance with 45 CFR 164.522.
	2. Permissible Requests by Participant. Participant will not ask AQI 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 Agreement, request that AQI Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of AQI, as provided for in 45 CFR 164.504(e)(4).
2. **TERM AND TERMINATION**
	1. Term. This Agreement 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 Agreement 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 Agreement unnecessary.
	2. Termination for Material Breach. Either Party may terminate this Agreement based upon a material breach of this Agreement 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 Agreement 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 Agreement immediately and without any notice.
	3. Termination Permitted Due to Change in Law. Either Party may terminate this Agreement as permitted in accordance with Section 8(b) of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law.
	4. Effect of Termination.
		* 1. Except as provided in paragraph (ii) of this Subsection and except with respect to Limited Data Set Information, upon termination of this Agreement for any reason, AQI will return or destroy all PHI received from Participant, or created or received by AQI on behalf of Participant. AQI 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.
			2. In the event that AQI reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, AQI will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a Database, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, AQI will extend the protections of this Agreement 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 AQI maintains such PHI.
			3. The Parties acknowledge and agree that the provision of any PHI to AQI in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to AQI, and AQI 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 Agreement, 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.
			4. The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.
3. Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. 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 Agreement.
4. ***MISCELLANEOUS***
	1. Regulatory References. A reference in this Agreement 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.
	2. Amendment. This Agreement 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 Agreement from time to time if necessary for Participant and/or AQI 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 Agreement, 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 Agreement in violation of such law or regulation or adversely affects the Parties’ abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.
	3. Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and AQI to comply with the HIPAA Regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.
	4. Third Party Beneficiaries. AQI and Participant agree that Individuals whose PHI is Used or Disclosed to AQI or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.
	5. Waiver. No provision of this Agreement 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.
	6. Correspondence. The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

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

THE ANESTHESIA QUALITY INSTITUTE

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By:

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

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

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

PARTICIPANT

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

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

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

Corporation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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