THIS PARTICIPATION AGREEMENT (the “Agreement”) is made and entered into by and between the American Association of Cardiovascular and Pulmonary Rehabilitation (“AACVPR”), a non-profit corporation, whose main office is located at 330 N. Wabash Avenue, Suite 2000, Chicago, IL 60611 and [INSERT CORRECT LEGAL ENTITY NAME OF PARTICIPANT] (“Participant”).

WHEREAS, AACVPR is a not-for-profit, tax-exempt association whose purpose includes the reduction of morbidity, mortality and disability from cardiovascular and pulmonary disease through education, research and disease management;

WHEREAS, AACVPR has established a national database for outpatient pulmonary rehabilitation program outcome benchmarking through the Outpatient Pulmonary Rehabilitation Registry (“Registry”);

WHEREAS, the purpose of the Registry is to provide benchmarks, promulgate data useful for quality assessment and improvement, and improve overall care provided to patients in outpatient pulmonary rehabilitation programs;

WHEREAS, Participant is a healthcare entity that desires to contribute data to the Registry.

In consideration of the mutual covenants and premises herein contained, the parties agree as follows:

I. DATA CONTRIBUTION

1.1. Participant’s Contribution of Data. Participant agrees to contribute certain data, as established by AACVPR from time to time and communicated to all Registry participants through updates to the Registry website or direct communication to participants (the “OPR
Participant must submit the OPR Data in accordance with the data reliability standards established by AACVPR. Participant agrees to submit data in the format as required by AACVPR.

1.2. **License to Use Data.** Participant represents and warrants that Participant has the right to the OPR Data and is legally authorized and permitted by all applicable state and federal laws to submit the OPR Data to the Registry. Participant understands and agrees that Participant’s identity will be removed and its OPR Data will be aggregated with data contributed by other participants. The aggregated database will be used to create benchmarking data and facilitate collaborative research related to healthcare quality. Accordingly, Participant grants to AACVPR a non-exclusive, irrevocable, perpetual license to use Participant’s OPR Data for the purpose of aggregating it with other participants’ data (“Aggregated Registry Data”) and sharing it with other participants for purposes of research and benchmarking for the benefit of participants’ quality improvement activities. AACVPR will share Participant’s OPR Data with other participants in a way that will not separately identify Participant’s OPR Data except to Participant as described in Section 2 of this Agreement or if Participant grants permission to AACVPR in writing.

1.3. **Registry and Aggregated Data.** Notwithstanding the ownership rights of Participant in Participant’s own OPR Data, AACVPR owns all right, title, and interest in the Registry and the Aggregated Registry Data contained therein, including all intellectual property rights therein. AACVPR hereby grants to Participant a limited, non-exclusive revocable license to utilize Benchmarking Reports (as defined below) for appropriate internal purposes only and in accordance with Section 4.2 of this Agreement.

1.4. **Principal User.** Participant agrees to designate a Principal User who will be responsible for accurately collecting and reporting the data elements and complying with the requirements as described in Exhibit A attached hereto and incorporated herein by reference and subject to change from time to time. Participant agrees to identify the Principal User to act as the contact person for communications with AACVPR regarding the Registry and the Principal User will promptly respond to reasonable communications and requests from AACVPR related to the Registry. The Principal User will be responsible for training Participant’s staff and verifying that the data has been accurately collected and entered into the Registry. AACVPR will provide training to Principal User.

1.5. **Limitations.** Except for the license rights expressly granted herein, no express or implied license, right or interest in or to any intellectual property of AACVPR or the Registry is conferred by this Agreement. Participant shall not remove any proprietary rights notice from the Registry or any deliverable or product provided to Participant by AACVPR or the Registry. Any portion of the Registry or its content merged into or used in conjunction with other material will continue to be the property of AACVPR and subject to the terms and conditions of this Agreement. Any use of the Registry not expressly permitted by this Agreement is prohibited. Without limiting the foregoing, Participant shall not, except as otherwise provided herein, (a) install or configure the Registry other than in accordance with AACVPR’s specifications; (b) reverse assemble, reverse compile, reverse engineer or otherwise attempt to write the source code of the Registry; (c) modify, enhance or create derivatives of the Registry; or (d) lease,
sublease, sublicense, sell, distribute, transfer possession, rent, or grant other rights in the Registry.

1.6. Audits. In order to monitor the quality of the OPR Data entered into the Registry, Participant agrees that AACVPR or its agents may from time to time conduct on-site audits of Participant’s data and collection procedures. AACVPR will provide at least ten (10) business days’ notice of an on-site audit. To the extent medical records are needed to conduct the audit, AACVPR will request and Participant will provide only the minimum necessary portions of the record required for the audit. If the audit demonstrates that Participant is not properly submitting the OPR Data, AACVPR may require additional audits for an additional fee as reasonably determined by AACVPR.

II. REPORTS PROVIDED BY AACVPR

2.1. Benchmarking Reports. Participant shall have the ability to create certain benchmarking reports based on an analysis of Participant’s individual OPR Data compared to the Aggregated Registry Data (“Benchmarking Reports”). The Benchmarking Reports will be in a format developed by AACVPR and subject to change from time to time. Participant shall have access to the Registry and Benchmarking Reports only so long as (i) Participant has paid all fees required in Section 3 of this Agreement; (ii) Participant has contributed and is contributing OPR Data to the Registry in accordance with data collection protocols; and (iii) this Agreement is in effect.

III. FEES

3.1. Fees. Participant agrees to pay AACVPR an annual fee for participation in the Registry as described on Exhibit B attached hereto and incorporated herein by reference. Participant shall pay additional fees as described in Section 1.6 of this Agreement, as applicable. AACVPR may revise the annual fee for all participants pursuant to a fee schedule change that will be provided to all participants.

3.2. Timing of Payment. Participant shall pay the annual fee for participation for each year, in advance. Participant shall pay for the first year of the participation upon receipt of a fully executed Agreement. Thereafter, AACVPR will provide an invoice at least thirty (30) days prior to the end of the Initial or Renewal Term, whichever is applicable. Payment is due on or before June 30, as described in Exhibit B.

IV. PUBLICATIONS

4.1. Publications. Participant agrees that AACVPR may publicize Participant’s name along with a list of other participants on AACVPR’s website and other materials listing the participants in the Registry. Participant may use AACVPR’s name and the name of the Registry only in connection with a general internal or external statement publicizing Participant’s participation in the Registry. Any other press release, advertising, promotional sales literature or other promotional written statements or promotional oral statements to the public in connection with or alluding to the Registry or the relationship between the parties created by this Agreement that has or contains any reference to AACVPR, or the name of any member of AACVPR’s staff is prohibited without the prior written approval of AACVPR.
4.2. **Use of Reports.** Participant shall only use Benchmarking Reports and Aggregated Registry Data for internal quality improvement purposes only. Participant shall not disclose Benchmarking Reports or Aggregated Registry Data without written permission of AACVPR. Participant shall comply with all publishing guidelines established by AACVPR from time to time regarding permitted uses and disclosures of Benchmarking Reports and Aggregated Data.

V. **PROTECTION OF CONFIDENTIAL INFORMATION**

5.1. **Confidential Information Defined.** “Confidential Information,” as used herein, means any or all information or proprietary materials (in every form and media) not generally known in the relevant trade or industry and which has been or is hereafter disclosed or made available by either party (the “Disclosing Party”) to the other (the “Receiving Party”) in connection with this Agreement and Participant’s participation in the Registry, including but not limited to: (i) all trade secrets; (ii) existing or contemplated products, services, designs, technology, processes, technical data, engineering, techniques, methodologies and concepts and any information related thereto; (iii) information relating to business plans, sales or marketing methods and customer lists or requirements. “Confidential Information” shall not include (a) any information which is or becomes publicly known through no breach of this Agreement; (b) any information lawfully received by a third party who has lawful right to disclose; (c) any information which is independently developed by the Receiving Party and such independent development is documented; or (d) any information which is required to be disclosed pursuant to law, rule, regulation or court order, provided, however, that the Receiving Party gives the Disclosing Party prompt notice upon learning of such disclosure obligation and the Receiving Party only discloses the minimum amount of information necessary to be in compliance with such law, rule, regulation or court order.

5.2. **Confidential Information.** Each party acknowledges that any Confidential Information shall be held in confidence. Each party agrees that it will use at least the same effort to prevent disclosure of the other party’s Confidential Information as it uses to protect its own Confidential Information, which shall be no less than a reasonable effort. Each party will limit its disclosure and use of the other party’s Confidential Information to those of its employees, consultants and agents as having a need to know such information and who have agreed to maintain the confidentiality of such information in the manner consistent with this Agreement. Each party agrees that it may only use the Confidential Information for the purposes for which it was originally disclosed and only in accordance with the terms and conditions of this Agreement.

5.3. **Injunctive Relief.** Each party acknowledges that any disclosure of Confidential Information in violation of this Agreement is likely to cause serious and irreparable harm, the amount of which may be extremely difficult to estimate, thus making any remedy at law or in damages inadequate. Each party therefore agrees that if the other party breaches this Agreement with respect to the disclosure of Confidential Information or if such party has cause to believe that the other party intends to or is about to commit such a breach of this Agreement, then such party shall have the right to obtain an injunction to halt or prevent such breach.
5.4. **Confidentiality of Participant’s Identity.** AACVPR will not release Participant’s OPR Data in any format or circumstance that identifies Participant or its medical or professional staff or employees as the contributor of its specific OPR Data, except to the Participant, as required by legal process, or as specifically authorized by Participant. If any legal demand for Participant’s OPR Data is made upon AACVPR, AACVPR will promptly notify Participant so that Participant may, at its option, challenge the validity of the legal process. The provisions of this Section shall survive any termination or expiration of this Agreement.

V I . **TERM AND TERMINATION**

6.1. **Term.** This Agreement will begin on the later of the signature dates indicated in the signature blocks below (“Effective Date”) and will continue until June 30 of the following year (the “Initial Term”); this Agreement shall automatically renew for additional periods of one (1) year (each, a “Renewal Term”) and will continue until (i) AACVPR provides notice of non-renewal thirty (30) days prior to the end of the Renewal Term or (ii) terminated under Section 6.2 of this Agreement.

6.2. **Termination.** AACVPR reserves the right to terminate this Agreement upon thirty (30) days prior written notice to Participant, if Participant materially fails to fulfill the terms of the Agreement or materially violates its conditions. Participant may terminate this Agreement at any time. AACVPR may also terminate this Agreement prior to the end of the applicable Initial or Renewal Term if AACVPR suspends data collection. Regardless of the reason for termination, AACVPR will not refund any fees and Participant will be obligated to pay all fees applicable for the current Initial or Renewal Term.

6.3. **Effect of Termination.** The provisions of Sections 1.3, 4.2, 5, 7.8, 8, 9.6, 9.7, 9.9, and 9.13 shall survive termination or expiration of this Agreement for any reason whatsoever.

V I I . **BUSINESS ASSOCIATE AND DATA USE PROVISIONS**

7.1. **General Provisions.** Participation in the Registry requires Participant to Disclose to AACVPR and for AACVPR to Use and Disclose patient Protected Health Information (“PHI”), including Electronic Protected Health Information (“EPHI”), as those terms are defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and the regulations issued thereunder (collectively, the “HIPAA Regulations”). These Uses and Disclosures are for purposes of conducting data analyses that relate to Participant’s Health Care Operations, including but not limited to Data Aggregation and quality assessment. The Registry also may from time to time require the Disclosure of PHI in the form of a Limited Data Set for AACVPR to provide services to Participant related to its Health Care Operations and for Research purposes. The HIPAA Regulations require Participant and AACVPR to enter into a Business Associate Agreement and a Data Use Agreement to protect PHI and EPHI and Limited Data Sets. The parties agree that the provisions of this Section 7 constitute a Business Associate Agreement and a Data Use Agreement.
7.2. Definitions. Capitalized terms used but not otherwise defined in this Agreement will have the meaning ascribed to them in the HIPAA Regulations. PHI and EPHI will have the meaning ascribed to them in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to AACVPR or a Subcontractor of AACVPR, or created by AACVPR or its Subcontractor on behalf of Participant. Unless otherwise specified, PHI will include EPHI for purposes of this Agreement. Limited Data Set will have the meaning ascribed to “Limited Data Set” in the Privacy Rule, but for the purposes of this Agreement will refer solely to Limited Data Sets transmitted from or on behalf of Participant to AACVPR or a Subcontractor of AACVPR, or created by AACVPR or its Subcontractor on behalf of Participant. The parties agree that AACVPR is a Business Associate and Participant is a Covered Entity under the terms of the HIPAA Regulations.

7.3. Specific Permitted Uses and Disclosures. Except as otherwise specified in this Agreement, AACVPR 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, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. Without limiting the generality of the foregoing, Participant further agrees that AACVPR may Use and Disclose the PHI received for the following specific purposes:

(a) To analyze, aggregate, produce and publish data on clinical patterns of diagnosis, treatment and outcomes of patients to assist with Health Care Operations;

(b) To produce reports of aggregated, de-identified data and data not identifiable by contributing Participant that describe the diagnosis, treatment and outcomes of patients to assist with Health Care Operations;

(c) To evaluate Participant performance, develop effective interventions to improve outcomes at the national and local level, and provide feedback in the form of an individual participant’s OPR Data benchmarked against regional and national OPR Data to assist with Health Care Operations; and

(d) To create, Use and share Limited Data Sets with Registry participants and with other researchers for Research in the area of health care, subject to Subsections 7.4(f) and 7.6 below.

7.4. General Uses and Disclosures.

(a) Except as otherwise limited in this Agreement, AACVPR may Use PHI for the proper management and administration of AACVPR or to carry out the legal responsibilities of AACVPR.

(b) Except as otherwise limited in this Agreement, AACVPR may Disclose PHI for the proper management and administration of AACVPR, provided that Disclosures are Required By Law, or AACVPR otherwise obtains reasonable assurances from the person to whom the PHI is disclosed that the person will (i) protect the confidentiality and security of the PHI, (ii) Use or further Disclose it only as Required By Law or for the purpose for which it was
disclosed to the person, and (iii) notify AACVPR of any instances of which the person is aware that the confidentiality or security of the PHI has been breached.

(c) Nothing in this Agreement will be interpreted to prevent AACVPR from Disclosing PHI in accordance with the HIPAA Regulations, 45 CFR 164.502(j)(1), concerning Disclosures in the public interest, or other permissible Uses or Disclosures by a Business Associate as set forth in the HIPAA Regulations.

(d) Except as otherwise limited in this Agreement, AACVPR may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(e) AACVPR 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. AACVPR 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 otherwise consistent with this Agreement.

(f) AACVPR 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).

7.5. Obligations of AACVPR as Business Associate.

(a) AACVPR agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.

(b) AACVPR agrees to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to EPHI to prevent Use or Disclosure of PHI by AACVPR or its Subcontractors other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the EPHI that AACVPR creates, receives, maintains or transmits on behalf of Participant. Without limiting the foregoing, AACVPR and/or its Subcontractors will, at its own expense, provide the equipment and software services necessary to reasonably protect and safeguard the PHI consistent with industry standards of similarly situated business associates.

(c) AACVPR agrees to promptly report to Participant any Use or Disclosure of PHI not authorized by this Agreement of which it becomes aware and any Security Incident of which it becomes aware.

(d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), AACVPR agrees to ensure that any Subcontractors that create, receive, maintain, or transmit PHI or EPHI on behalf of AACVPR agree to comply with the same restrictions and conditions that apply to AACVPR through this Agreement, including the implementation of reasonable and appropriate safeguards to protect EPHI and the provisions of Section 7.6 below.
(e) AACVPR agrees to make its internal practices, books and records relating to the Use and Disclosure of PHI and EPHI received from, or created or received by AACVPR on behalf of Participant and AACVPR’s Administrative, Physical and Technical Safeguards for EPHI, available to the Secretary of the U.S. Department of Health and Human Services (“Secretary”), during reasonable business hours, for purposes of the Secretary determining Participant’s compliance with the HIPAA Regulations.

(f) If PHI provided to AACVPR constitutes a Designated Record Set, AACVPR 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 AACVPR or its Subcontractor directly about gaining access to his or her PHI, AACVPR will not provide such access but rather will promptly forward such request to Participant.

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

(h) AACVPR 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, AACVPR agrees to provide promptly to Participant or an Individual, upon Participant’s reasonable request, information collected in accordance with this subsection 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 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.

(i) In the event of an unauthorized Use or Disclosure that constitutes a Breach of Unsecured PHI, AACVPR will notify Participant without unreasonable delay but in no event later than sixty (60) calendar days following the Discovery of such Breach. Such notice shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by AACVPR to have been, accessed, acquired, used, or disclosed during the Breach, and such other available information as is required to be included in the notification to the individual under 45 CFR 164.404(c).

(j) To the extent that AACVPR is to carry out one or more of Participant’s obligation(s) under Subpart E of 45 CFR Part 164, AACVPR agrees to comply with the requirements of Subpart E that apply to Participant in the performance of such obligation(s).
7.6 Data Use Agreement Obligations. With respect to the Limited Data Sets that AACVPR may create, Use and Disclose for Research purposes pursuant to Sections 7.3(d) herein, AACVPR agrees that it:

(a) Will Use the Limited Data Set only for such Research purposes and will Disclose the Limited Data Set only to participants in the Registry and other researchers for Research in the area of health care in accordance with the provisions of 45 CFR 164.512(i);

(b) Will not Use or further Disclose the Limited Data Set in a manner that would violate the HIPAA Regulations if done by Participant;

(c) Will not Use or Disclose the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law;

(d) Will use reasonable and appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314;

(e) Will promptly report to Participant any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware and any Security Incident involving the Limited Data Set of which it becomes aware;

(f) Will ensure that any Registry participants or other researchers, and any Subcontractors to whom it provides the Limited Data Set, contractually agree to the same restrictions and conditions that apply to AACVPR with respect to such information; and

(g) Will not use the Limited Data Set to identify or contact the Individuals who are the subject of the information. Nothing in this subsection will be interpreted to limit AACVPR’s ability to provide its Data Aggregation and analysis services as otherwise provided by this Agreement.

7.7 Obligations of Participant.

(a) 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 AACVPR with a copy of its Notice of Privacy Practices upon request.

(b) Participant shall notify AACVPR of any limitation(s) in Participant’s Notice of Privacy Practices, to the extent that such limitation may affect AACVPR’s Use or Disclosure of PHI.

(c) Participant represents and warrants that, as of the Effective Date, all Disclosures of PHI made to AACVPR are permissible Disclosures under the HIPAA Regulations and applicable state law, and no Individual has restricted Disclosure so as to make the Disclosure to AACVPR impermissible. Participant will notify AACVPR of any restriction on the Use or
Disclosure of PHI that Participant has agreed to in accordance with the HIPAA Regulations, 45 CFR 164.522, if such restriction affects AACVPR’s Use or Disclosure of PHI.

(d) Participant will not ask AACVPR 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 AACVPR Use or Disclose PHI for the purposes of Data Aggregation or the proper management and administrative activities of AACVPR or to carry out the legal responsibilities of AACVPR, as provided for in 45 CFR 164.504(e)(4).

7.8 Effect of Termination on AACVPR’s Obligation to Destroy or Protect Data. Except as provided below, upon termination of this Agreement, for any reason, AACVPR will, at Participant’s direction, return or destroy all PHI received from Participant, or created or received by AACVPR on behalf of Participant, and AACVPR will retain no copies of the PHI. Data contained in a Limited Data Set shall not be subject to the obligations of this section and the Data Use provisions pertaining to such Limited Data Set that are set forth above will survive any termination or expiration of the Agreement. In the event that AACVPR reasonably determines that returning or destroying the PHI is infeasible due to inclusion of the PHI in the Registry or for other legitimate reason, AACVPR will give Participant a statement of reasons why the return or destruction of the PHI is infeasible. As the sole consequence of such determination, AACVPR will extend the protections of this Agreement to such PHI and limit further its Use and Disclosure to those purposes that make the return or destruction infeasible, for so long as AACVPR maintains such PHI. The obligations of this section will survive any termination or expiration of this Agreement.

VIII. NO WARRANTIES; LIMITATION OF LIABILITY

8.1. Disclaimer of Warranty. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE REGISTRY AND ANY AND ALL MATERIALS DEVELOPED BY AACVPR UNDER THIS AGREEMENT ARE PROVIDED “AS IS” WITH ALL FAULTS, AND AACVPR DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE REGISTRY AND AACVPR MATERIALS DEVELOPED HEREUNDER, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, NON-INFRINGEMENT, OR THAT THE REGISTRY AND AACVPR MATERIALS DEVELOPED HEREUNDER WILL OPERATE ERROR FREE, UNINTERRUPTED OR BE FREE OF VIRUSES. THE ENTIRE RISK AS TO THE SELECTION, SATISFACTION, QUALITY AND PERFORMANCE AND USE OF THE REGISTRY SHALL BE WITH PARTICIPANT.

8.2. Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL AACVPR BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR EXEMPLARY DAMAGES (INCLUDING DAMAGES RELATED TO DELAYS, LOSS OF DATA, INTERRUPTION OF SERVICE OR LOSS OF USE, BUSINESS, REVENUE OR PROFITS) IN CONNECTION WITH THIS AGREEMENT, USE OR INABILITY TO USE THE REGISTRY, UNDER ANY LEGAL THEORY, EVEN IF AACVPR HAS BEEN ADVISED OF THE POSSIBILITY OF
SUCH DAMAGES. IN NO EVENT SHALL AACVPR BE LIABLE FOR ANY THIRD PARTY CLAIM. LIABILITY FOR DAMAGES SHALL BE LIMITED AND/OR EXCLUDED AS PROVIDED IN THIS AGREEMENT, EVEN IF ANY EXCLUSIVE REMEDY PROVIDED FOR IN THIS AGREEMENT FAILS OF ITS ESSENTIAL PURPOSE.

10. ADDITIONAL TERMS

9.1. Force Majeure. Neither party shall be liable for failure to meet any requirements of this Agreement, and this Agreement may not be terminated for such cause, if such failure is due to electrical outage, strike, natural disaster, or any other event beyond the control of the party, which makes performance impossible or impractical.

9.2. Amendment. Any amendment to this Agreement must be in writing and signed by each of the parties. The parties agree to amend this Agreement from time to time as necessary for the parties to comply with the requirements of federal and applicable state law. Provided, however, that AACVPR may make changes to the Registry and data collected from time to time by giving notice to all Participants as soon as is practicable prior to their implementation and any such changes will not be considered an amendment to this Agreement.

9.3. Assignment. Neither party may, without the written consent of the other, assign, delegate or otherwise transfer this Agreement or any of its rights or obligations under this Agreement.

9.4. Severability. If any part of this Agreement is determined to be invalid, illegal or unenforceable by any Act of Congress, state legislature or by any regulation issued by the United States or a State, or declared null and void by any court with valid jurisdiction, then the parties will modify such part, if possible, to conform to the law, and the remaining parts will be fully effective and operative insofar as reasonably possible.

9.5. Entire Agreement. This Agreement, including its attachments and exhibits, if any, constitutes the entire understanding and agreement between the parties concerning the subject matter of this Agreement, and supersedes all prior negotiations, agreements, and understandings between the parties, whether oral or in writing, concerning its subject matter.

9.6. Jurisdiction. This Agreement is governed by the laws of the State of Illinois and venue for resolution of any disputes shall reside in the federal or state courts in Cook County, Illinois. Each party consents to the personal jurisdiction of the federal and state courts located in Cook County, Illinois.

9.7. Third Party Beneficiaries. The parties do not intend to create any third party beneficiaries to this Agreement. Without the limiting the foregoing, the parties state that the individuals whose PHI is Used or Disclosed to AACVPR or its Subcontractors under this Agreement are not third party beneficiaries to this Agreement.

9.8. Waiver. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any item or provision shall not be construed as a waiver of any other term or provision.
9.9. **Relationship of The Parties.** The parties are independent contractors of each other. Nothing in this Agreement shall be construed to create a fiduciary relationship, partnership, employer/employee joint venture, agency or other similar relationship between the parties. Neither party shall have the right to exercise control or direction over the business of the other party.

9.10. **Authority.** The undersigned represents and warrants that they are authorized to enter into this Agreement on behalf of the party he or she represents, and that this Agreement will be binding on such party, and its officers, directors, agents, and employees.

9.11. **Interpretation.** Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and AACVPR to comply with HIPAA and applicable state and federal laws and regulations.

9.12. **Notices.** Any notices required pursuant to this Agreement shall be in writing and sent by US Mail, personal delivery, next-day express mail, or by facsimile addressed as identified below:

If to AACVPR:

AACVPR Registry  
330 N. Wabash Ave, Suite 2000  
Chicago, IL 60611

If to Participant:

______________________________
______________________________
______________________________

9.13. **Survival.** All provisions of this Agreement relating to warranties, confidentiality, nondisclosure, proprietary rights, limitation of liability, and payment obligations shall survive the termination or expiration of this Agreement.

**IN WITNESS WHEREOF,** the parties have each executed this Agreement by their duly authorized representative on the dates shown below.

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The “Principal User” for the AACVPR Registry will be an individual selected by the Participant. The main function of the Principal User is to ensure that patient and program data complies with registry definitions and security requirements and to act as the main contact between AACVPR and the Participant. Specifically, the Principal User will:

1. Participate in at least one Registry training webcast/webinar and/or complete the online training module and any significant updates to the Registry protocols as determined by AACVPR.
2. Ensure that all Participant data entered by way of either the web-based interface or third-party software conform to the specific definitions and collection periods as defined by AACVPR.
3. Ensure that the Participant utilizes all necessary security precautions to ensure data integrity and security.
4. Ensure that all staff who will or may be entering data into the Registry are sufficiently trained to ensure compliance with data validity and security.
5. Act as a contact source between AACVPR and the Participant regarding any general registry communications, updates, troubleshooting, or data inquiries.
6. Notify AACVPR as soon as possible regarding data entry errors, software problems, bugs, or other problems that would compromise the validity and/or security of the member’s data or of the Registry as a whole.
7. Notify AACVPR of a change in the Principal User.
Participants will pay an annual fee based on program size. Subscriptions will be renewable each year by June 30th. Program size is based on the number of Phase 2 patients in the program annually. If your check is mailed separately from this agreement, this Exhibit B must be included with the check to ensure timely processing. You may also pay by credit card online.

Program Name: __________________________________________

Program Address: _______________________________________

Registry Principal User: _________________________________

Please check the appropriate category below:

Payment Received between: April 1 – December 31 – 12 month subscription fee valid through June 30 of following year.

☐ Annual enrollment of more than 75 patients: $225/ year
☐ Annual enrollment of 25-75 patients: $200/ year
☐ Annual enrollment of fewer than 25 patients: $175/ year

Payment Received between: January 1 – March 31 – 18 month subscription fee valid through June 30 of following year.

☐ Annual enrollment of more than 75 patients: $335/ year
☐ Annual enrollment of 25-75 patients: $300/ year
☐ Annual enrollment of fewer than 25 patients: $260/ year

*Subscriber renewal notices will be sent each spring no later than May 1.*