



A.S.P.E.N.'s National Patient
Registry for Nutrition Care

Sustain™, LLC

PARTICIPATION AND DATA USE AGREEMENT

THIS PARTICIPATION AGREEMENT (the “Agreement”) is made and entered into by and between Sustain™, LLC, an Illinois limited liability company that is a wholly owned affiliate of the American Society for Parenteral and Enteral Nutrition (“Sustain”), and the individual or entity identified below (“Participant”).

WHEREAS, A.S.P.E.N. is a not-for-profit, tax-exempt association whose purpose includes the improvement of patient care by advancing the science and practice of nutrition support therapy; and; and

WHEREAS, A.S.P.E.N. has established and owns Sustain, LLC, a national nutrition care registry to gather data to maintain a prospective, longitudinal nutrition therapy patient registry for the purpose of improving patient outcomes. (“Registry”); and

WHEREAS, the first phase of the Registry will collect information regarding patients and populations who require home parenteral nutrition in the U.S. to measure outcomes, to allow institutional benchmarking against aggregated data, and publish findings; and

WHEREAS, Participant is a medical center, hospital, home infusion provider, medical group, or other health care entity that desires to contribute data to the Registry.

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

1. TERM AND TERMINATION

1.1 Term of Agreement. This Agreement will begin on later of the signature dates indicated in the signature blocks below and will continue for an initial period of one (1) year (the “Initial Term”); this Agreement shall automatically renew for additional periods of one (1) year (each, a “Renewal Term”) and will continue until terminated, as provided herein.





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1.2 Termination. Sustain may terminate this Agreement upon termination of the Registry program or upon thirty (30) days written notice to Participant. Participant may terminate this Agreement on thirty (30) days written notice to Sustain.

2. DATA CONTRIBUTION.

2.1 IRB Approval. Upon execution of this Agreement, Sustain will provide a copy of the registry protocol established by Sustain for the Registry project (the "Protocol"). Participant acknowledges and agrees that it shall have sole responsibility to obtain any internal approvals necessary for participation in the Registry, including Institutional Review Board ("IRB") approval or waiver, as may be required under the policies and procedures of the Participant. To the extent applicable, Participant will be solely responsible for obtaining any necessary informed consent documents that may be required by Participant's IRB.

2.2 Participant's Contribution of Data. Participant agrees to contribute the data elements described in the "Data Collection Tool" established by Sustain from time to time (the "Data") to the Registry. Participant shall follow the Protocol's instructions regarding blinding of patient identifiers such that the Data constitutes no more than a "Limited Data Set" as defined by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). Sustain may revise data elements, including their format, and the frequency of required contributions from time to time, provided that the Registry will remain a Limited Data Set. Sustain will provide reasonable advance notice of any revisions to all Registry participants through updates to the Registry website or other direct communication to participants. Participant agrees that it is solely responsible for the complete, accurate, and timely submission of Participant's Data to the Registry.

2.3 Leadership; Access Controls. Participant agrees to identify one individual to act as the "Site Investigator," who will be the primary contact person for communications with Sustain regarding the Registry. Participant will ensure that the Site Investigator promptly responds to all reasonable communications and requests from SUSTAIN related to the Registry. Participant agrees to comply with any access control policies established by Sustain and communicated to Participant with respect to user IDs, passwords, and software, which may be revised or updated by Sustain from time to time.

2.4 License to Use Data. Participant represents and warrants that Participant is legally authorized to submit the Data to the Registry. Participant's Data will be de-identified





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as to Participant's identity and aggregated with data contributed by other participants to create an aggregated database, which will be used to create benchmarking data and facilitate collaborative research. Accordingly, Participant grants to SUSTAIN a continuous, irrevocable, non-exclusive license to use Participant's Data for the purpose of aggregating it with other participants' data ("Aggregated Registry Data") and using the Aggregated Registry Data for research, public health, and/or health care operations.

2.5 Registry and Aggregated Data. Notwithstanding the ownership rights of Participant in Participant's own Data, SUSTAIN owns all right, title and interest in and to the Registry and the Aggregated Registry Data contained therein, including all associated intellectual property rights. SUSTAIN grants a non-exclusive, revocable, non-transferable license to Participant to use the Registry to obtain the summaries and benchmarking data provided to Participant in connection with the Registry. Participant's license to use the Aggregated Registry Data and the Registry shall terminate concurrent with termination of this Agreement.

2.6 Limitations. Except for the license rights expressly granted herein, no express or implied license, right or interest in or to any intellectual property of Sustain 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 Sustain 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 Sustain 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 Sustain'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; (d) lease, sublease, sublicense, sell, distribute, transfer possession, rent, or grant other rights in the Registry.

3. REPORTS PROVIDED BY SUSTAIN

3.1 Benchmarking Reports. From time to time, but no less than on a quarterly basis, Sustain will create and make available to Participant certain benchmarking reports based on an analysis of Participant's individual Data compared to the Aggregated Registry Data ("Benchmarking Reports"). The Benchmarking Reports will be in a format developed by Sustain from time to time. Participant shall have access to the Registry and





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Benchmarking Reports only during the Term of this Agreement and only so long as Participant has contributed Data to the Registry in connection with Data collection protocols and timeframes established by Sustain. If Participant fails to submit complete Data in a timely fashion, Sustain will not release Benchmarking Reports to Participant and may terminate this Agreement as provided herein.

3.2 Additional Reports. Participant may request unique reports from Sustain and Sustain will evaluate such requests and, if feasible, provide them to Participant in exchange for a reasonable fee as agreed to by the parties.

4. PUBLICATIONS

4.1 Publications. Participant agrees that Sustain may publicize its name along with lists of Participants in the Registry. Participant may use Sustain'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 Participant, Sustain, the Registry, the name of any member of Sustain's staff or the name of Participant is prohibited without the prior written approval of the other party.

4.2 Use of Benchmarking Reports. Participant agrees to comply with all publishing or use guidelines established by Sustain from time to time regarding permitted uses and disclosures of Benchmarking Reports. In general, Participant shall only use reports for appropriate internal and external purposes in a manner that is accurate and not misleading.

5. CONFIDENTIALITY

5.1 Confidentiality of Participant Identity. Sustain will not release or disclose Participant's Data in any format that identifies Participant as the contributor of any specific data except as required by legal process, or as requested by the Participant. If any legal demand for the Participant's Data is made upon Sustain, Sustain will, to the extent allowed by law, promptly notify Participant so that Participant may, at its option, challenge the validity of the legal process. The data elements collected will include demographic information identifying Participant. These data elements will be maintained by Sustain only





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for purposes of administration of Participant's participation in the Registry. All identifying information will be removed prior to contribution to the Registry and replaced by a random ID number. The key that matches the ID number to the Participants will be maintained by the Sustain executive director and his or her direct staff, who shall hold it in strict confidence and not disclose it to any third party or use it for any purpose other than as specifically permitted by this Section.

6. HIPAA Data Use Provisions.

6.1 Limited Data Set. The parties acknowledge that certain data elements requested as part of the Protocol and stored in the Registry may constitute Protected Health Information protected under HIPAA, including specifically, elements of dates. The parties acknowledge that the data elements exclude direct identifiers of the patient and therefore comprise a limited data set under HIPAA ("Limited Data Set"). Participant agrees to provide the Limited Data Set to Sustain for purposes of health care operations and research ("Authorized Purposes"). Sustain agrees that it will only use or disclose Participant's Data for the limited purposes described in this Agreement.

6.2 Uses and Disclosures by Sustain Sustain agrees to use and disclose the Limited Data Set to assist Participating Site in quality improvement and other health care operations, including benchmarking and reporting as described in the Protocol. Sustain may also use and disclose de-identified data contained in the Registry to conduct research, as defined by HIPAA. Sustain will not use or further disclose the information maintained in a Limited Data Set except as permitted by this Agreement or as otherwise required by law. Sustain agrees not to use the Limited Data Set in such a way as to identify or contact any individual whose data is included in the Limited Data Set. Sustain shall limit the use or receipt of the Limited Data Set to the individuals employed or engaged by Sustain who need the Limited Data Set for the performance of the Authorized Purposes.

6.3 Safeguards. Sustain will use appropriate safeguards to prevent the use or disclosure of the Limited Data Set provided by Participant, other than as permitted under this Agreement or as required by law.

6.4 Reporting. Sustain will report to Participant any use or disclosure of the Limited Data Set not provided for by this Agreement of which Sustain becomes aware.

6.5 Agents and Subcontractors. Sustain will ensure that any agents, including a





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subcontractor, to whom Sustain provides the Limited Data Set agrees to the same restrictions and conditions that apply to Sustain with respect to such information. Participating Site acknowledges that Sustain has engaged a third party vendor to house the Registry and Sustain represents that such vendor has agreed to the required restrictions and conditions as described in this Agreement.

6.6 De-Identified Information. Participating Site hereby grants Sustain permission to de-identify data contained in the Registry in conformance with HIPAA and to use or disclose such information in Sustain's discretion.

7. FEES

7.1 No Fees for Preliminary Stage. In exchange for Participant's assistance with the development of the Registry, Sustain will provide Benchmarking Reports at no fee to Participant, except for reasonable fees related to additional unique reports as agreed to by the parties.

7.2 Future Fees. The parties acknowledge and agree that Sustain may institute a reasonable participation fee in the future and Participant shall have the right to terminate this Agreement if Participant does not wish to continue under a fee-based program.

8. NO WARRANTY; 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 SUSTAIN UNDER THIS AGREEMENT ("SUSTAIN MATERIALS") ARE PROVIDED "AS IS" WITH ALL FAULTS, AND SUSTAIN DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE REGISTRY AND SUSTAIN MATERIALS DEVELOPED HEREUNDER, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, NON-INFRINGEMENT, OR THAT THE REGISTRY AND SUSTAIN 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 THE PARTICIPANT.





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8.2 LIMITATION OF LIABILITY.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL SUSTAIN 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 SUSTAIN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL SUSTAIN 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.

9. ADDITIONAL TERMS

9.1 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 applicable law. Provided, however, that Sustain may make changes to the Protocol, the Registry, and Data collected from time to time by giving notice to all Registry Participants as soon as is practicable prior to their implementation and any such changes will not be considered an amendment to this Agreement.

9.2 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.

9.3 Severability. If any part of this Agreement is determined to be invalid, illegal or unenforceable, 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.

9.4 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





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matter.

9.5 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.

9.6 Third Party Beneficiaries. The parties do not intend to create any third party beneficiaries to this Agreement.

9.7 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.

9.8 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.

9.9 Authority. The undersigned represent and warrant 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.

9.10 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 Sustain:

8630 Fenton Street, Suite 412,
Silver Spring, MD 20910
Fax:

If to Participant:





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Fax: _____





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9.11 Survival. All provisions of this Agreement relating to warranties, confidentiality, non-disclosure, proprietary rights, and limitation of liability, indemnification obligations 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 representatives on the date(s) shown below.

SUSTAIN, LLC

PARTICIPANT

[Print Company Name]

By: _____

By: _____

Title _____

Title: _____

Date: _____

Date: _____

