

BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT ("BAA") supplements that _____ ("Agreement") made by and between _____ ("Covered Entity"), and Journey Clinical, Inc. ("Business Associate") (Covered Entity and Business Associate are each referred to herein as a "Party," and collectively as the "Parties"), and is effective the later of the _____ and the date of the Agreement (the "Effective Date").

W H E R E A S

A. The Covered Entity is subject to, and must comply with, the provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended from time to time including Sections 13400 through 13424 of the Health Information Technology for Economic Clinical Health Act (the "HITECH Act") and the corresponding Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), Security Standards for the Protection of Electronic Protected Health Information (the "Security Rule"), and the Notification in the Case of Breach of Unsecured Protected Health Information (the "Breach Notification Rule"), each of which are incorporated herein by reference.

B. Business Associate is a contractor that provides services to the Covered Entity and that the Covered Entity deems to be a "business associate" under the Privacy Rule and/or Security Rule, and Business Associate wishes to commence or continue its business relationship with the Covered Entity under the Agreement.

C. Business associates are subject to, and must comply with, certain provisions of the Privacy Rule, the Security Rule and the Breach Notification Rule, as required by the HITECH Act.

D. Business Associate acknowledges that the Covered Entity must comply with HIPAA and its corresponding regulations, and that in order to achieve such compliance, the Agreement must contain certain satisfactory assurances that Business Associate will appropriately safeguard Protected Health Information and Electronic Protected Health Information (collectively referred to herein as "PHI") that it receives from, or creates or receives on behalf of, the Covered Entity.

E. The Covered Entity seeks certain assurances from Business Associate, and Business Associate wishes to provide such assurances to the Covered Entity, to help it achieve and maintain compliance with the Privacy Rule, Security Rule and Breach Notification Rule.

F. By this BAA, the Covered Entity and Business Associate wish to supplement the terms and conditions of the Agreement to include provisions required by the HITECH Act, the Privacy Rule, the Security Rule and the Breach Notification Rule in order to bring the relationship between the Parties into compliance therewith.

Now therefore, for and in consideration of the mutual covenants and agreements contained herein, the Covered Entity and Business Associate agree as follows:

ARTICLE I **DEFINITIONS**

Unless otherwise defined herein, terms used in this BAA have the same meanings as those terms defined in the Privacy Rule (45 C.F.R. § 160.103 and § 164.501), the Security Rule (45 C.F.R. Parts 160, 162 and 45 C.F.R. § 164.304), and the Breach Notification Rule (45 C.F.R. § 164.402).

ARTICLE II **PERMITTED USES AND DISCLOSURES OF PHI**

Pursuant to the Agreement, Business Associate provides certain administrative services (“Services”) for the Covered Entity that may involve the use and/or disclosure of PHI that may be obtained from Covered Entity. Except as otherwise specified herein, Business Associate may use or disclose such PHI only in accordance with the Privacy Rule and Security Rule (as applicable) and only to perform those functions, activities or services for, or on behalf of, the Covered Entity as specified in the Agreement, provided that use or disclosure would not violate (i) the Privacy Rule or Security Rule if done by the Covered Entity or (ii) the minimum necessary policies and procedures of the Covered Entity.

Business Associate may use and disclose PHI created or received by Business Associate on behalf of Covered Entity if necessary for the proper management and administration of Business Associate or to carry out Business Associate’s legal responsibilities, if (i) the disclosure is required by law, or (ii) Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that (1) the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the Business Associate will be notified of any instances of which the person is aware in which the confidentiality of the information is breached.

ARTICLE III **RESPONSIBILITIES OF BUSINESS ASSOCIATE**

With regard to its use and/or disclosure of PHI, Business Associate agrees to do the following:

3.1 *Use.* Business Associate agrees to use and/or disclose PHI only as permitted or required by this BAA or as otherwise required by law.

3.2 *Safeguards.* Business Associate will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the PHI that it creates, receives, maintains or transmits on behalf of Covered Entity, and that reasonably prevent the use or disclosure of the PHI except as described in this BAA. Business Associate shall comply, as applicable, with the requirements of the Security Rule.

3.3 *Reporting to Covered Entity.* Business Associate will report to the Covered Entity any security incident or use or disclosure of PHI of which it becomes aware that is not permitted or required by this BAA.

3.4 *Mitigation.* Business Associate agrees to mitigate, to the extent practicable, any harmful effect known to it resulting from a use or disclosure of PHI in violation of the terms of this BAA.

3.5 Agents. Business Associate agrees to require all of its subcontractors and agents that create, receive, maintain or transmit PHI under the Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of PHI and to implement the same safeguards to protect PHI that apply to Business Associate. Business Associate agrees to make available to Covered Entity at its reasonable request documentation evidencing its subcontractors' and agents' agreements described in the preceding sentence.

3.6 Access to Records. Except as protected by state or federal privilege, Business Associate agrees to make available all records, books, agreements, policies and procedures relating to the safeguards implemented and the use or disclosure of PHI to the Secretary of the Department of Health and Human Services (the "Secretary"), in a time and manner designated by the Secretary, for the purpose of determining the Parties' compliance with the Privacy Rule, Security Rule, Breach Notification Rule and/or the Enforcement Rule.

3.7 Documentation of Disclosures. Business Associate agrees to document the disclosures of PHI and information related to those disclosures that would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. Business Associate agrees to provide the Covered Entity with documentation of all of Business Associate's disclosures of PHI as and to the extent reasonably requested by Covered Entity to permit the Covered Entity to respond to an Individual's request for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

3.8 Access to Designated Record Set. Business Associate agrees to provide access to the Covered Entity, or to an Individual or an Individual's designee as directed by the Covered Entity, to PHI contained in a Designated Record Set in the time and manner designated by the Covered Entity. If an Individual requests an electronic copy of PHI maintained electronically in a Designated Record Set, Business Associate agrees to provide access to the Covered Entity, or to an Individual or an Individual's designee as directed by the Covered Entity, to PHI in a readable electronic form and format as agreed to by the Covered Entity and the Individual, with respect to the PHI maintained electronically in a Designated Record Set.

3.9 Amendments to Designated Record Set. Business Associate agrees to make any amendment(s) to PHI contained in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526.

3.10 Minimum Necessary. Business Associate agrees to request from the Covered Entity, and disclose to its subcontractors, agents or applicable third parties, only the minimum PHI necessary to fulfill a specific function required or permitted hereunder.

3.11 Covered Entity's Obligations under the Privacy Rule. To the extent that Business Associate is to carry out one or more of the Covered Entity's obligation(s) under the Privacy Rule, Business Associate agrees to comply with the requirements of the Privacy Rule that apply to the Covered Entity in the performance of such obligation(s).

3.12 Breach Notification. Business Associate shall, following the discovery of a breach of Unsecured PHI, notify Covered Entity of such breach without unreasonable delay and in no event later than sixty (60) calendar days after discovery of the breach. When notifying Covered Entity, Business Associate

shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used, or disclosed during the breach.

3.13 *De-identification.* Business Associate may use PHI to de-identify the information in accordance with 45 C.F.R. § 164.514. The parties agree that de-identified information does not constitute PHI and is not subject to the terms of this BAA.

ARTICLE IV **RESPONSIBILITIES OF THE COVERED ENTITY**

With regard to the use or disclosure of PHI by Business Associate, the Covered Entity hereby agrees to do the following:

- a. Inform Business Associate of any changes in, or revocation of, an Individual's consent or authorization to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.
- b. Notify Business Associate of any restriction to the use or disclosure of PHI in its notice of privacy practices to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- c. Request Business Associate to use or disclose PHI only in a manner permissible under the Privacy Rule or Security Rule if done by the Covered Entity.

ARTICLE V **TERM AND TERMINATION**

5.1 *Term.* This BAA shall become effective on the Effective Date and shall continue in effect until all of the PHI provided by the Covered Entity to Business Associate, or created or received by Business Associate on behalf of the Covered Entity, is (i) destroyed and documentation of such destruction is provided to the Covered Entity, (ii) returned to the Covered Entity or (iii) if it is infeasible to return or destroy such PHI, until protections are extended to such information in accordance with **Section 5.3**.

5.2 *Termination by the Covered Entity for Cause.* Upon the Covered Entity's knowledge of a material breach of this BAA by Business Associate with respect to the Privacy Rule, the Covered Entity shall provide Business Associate an opportunity to cure the breach or end the violation and terminate this BAA and the Agreement if Business Associate does not cure the breach or end the violation within the time period specified by the Covered Entity, or immediately terminate this BAA and the Agreement if Business Associate has breached a material term of this BAA and cure is not possible.

5.3 *Effect of Termination.* Except as otherwise provided in this **Section 5.3**, Business Associate agrees to return or destroy all PHI received from the Covered Entity, or created or received by Business Associate on behalf of the Covered Entity, upon termination of this BAA for any reason. Business Associate also agrees to provide the Covered Entity with documentation of the destruction of PHI. This provision shall also apply to PHI that is in the possession of subcontractors or agents of Business Associate. In the event that Business Associate determines that returning or destroying PHI is infeasible, Business Associate shall extend the protections of this BAA to such PHI and limit further uses and

disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

ARTICLE VI **MISCELLANEOUS**

6.1 *Regulatory References.* References in this BAA to a section in the Privacy Rule, Security Rule and/or Breach Notification Rule shall refer to the section in effect or as amended.

6.2 *Survival.* The respective rights and obligations of Business Associate and the Covered Entity under the provisions of this BAA shall survive termination of this BAA.

6.3 *Changes, Modifications or Alterations.* The Parties agree to take such action to amend this BAA from time to time as is necessary for the Parties to comply with the Privacy Rule, Security Rule and/or Breach Notification Rule. No changes or modifications of this BAA shall be valid unless the same shall be in writing and signed by both Covered Entity and Business Associate.

6.4 *Counterparts.* This BAA may be executed in any number of counterparts, each of which shall be deemed an original, but all such counterparts together shall constitute one and the same instrument. Facsimile copies hereof shall be deemed to be originals.

6.5 *Interpretation.* Any ambiguity in this BAA shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, as applicable.

6.6 *Governing Law.* This BAA shall be interpreted, construed and enforced pursuant to and in accordance with the laws of the State of New York, without regard to its conflicts of law principles.

6.7 *Notices.* Any notice required or permitted to be given hereunder shall be in writing and shall be (i) personally delivered, (ii) transmitted by postage pre-paid first class certified United States mail, (iii) transmitted by pre-paid, overnight delivery with delivery tracking service, or (iv) transmitted by facsimile transmission. All notices and other communications shall be deemed to have been duly given, received and effective on (i) the date of receipt if delivered personally, (ii) three (3) business days after the date of posting if transmitted by mail, (iii) the business day after the date of transmission if by overnight delivery with proof of delivery, or (iv) if transmitted by facsimile transmission, the date of transmission with confirmation by the originating facsimile transmission machine of receipt by the receiving facsimile machine of such transmission, addressed to the Parties at the addresses below:

As to Covered Entity:	As to Business Associate:
Attn:	

or to such other address, or to the attention of such other person(s) or officer(s), as either Party may designate by written notice to the other Party.

6.8 Incorporation. Any provisions now or hereafter required to be included in this BAA by applicable state or federal law, including without limitation, the Privacy Rule, the Security Rule, the Breach Notification Rule and the HITECH Act, or by the U.S. Department of Health and Human Services or the Centers for Medicare and Medicaid Services shall be binding upon and enforceable against the Parties and be deemed incorporated herein, irrespective of whether or not such provisions are expressly set forth in this BAA or elsewhere in the Agreement.

6.9 Severability. The provisions of this BAA shall be deemed severable, and, if any portion shall be held invalid, illegal or unenforceable for any reason, the remainder of the BAA shall be effective and binding upon the Parties.

6.10 Waiver. A waiver of any provision of this BAA must be in writing, signed by the Parties hereto. The waiver by either Party of any provision of this BAA or the failure of any Party to insist on the performance of any of the terms or conditions of this BAA shall not operate as, nor be construed to be, a waiver or the relinquishment of any rights granted hereunder and the obligation of the Parties with respect thereto shall continue in full force and effect.

6.11 Force and Effect. The Parties acknowledge and agree that this BAA shall be of no force and effect unless and until a duly authorized representative of each party has signed the following signature page where indicated.

IN WITNESS WHEREOF, the undersigned have caused this Business Associate Agreement to be duly executed as of the Effective Date.

COVERED ENTITY

By: _____

Print Name: _____

Print Title: _____

Date: _____

BUSINESS ASSOCIATE

By: _____

Print Name: _____

Print Title: _____

Date: _____