

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement"), effective April 16, 2015 ("Effective Date"), is entered into by and among the County of Monterey, a political subdivision of the State of California, on behalf of Natividad Medical Center ("Covered Entity") and Brainlab, Inc. ("Business Associate") (each a "Party" and collectively the "Parties").

Business Associate provides certain services for Covered Entity ("Services") that may involve the use and disclosure of Protected Health Information that is created or received by Business Associate from or on behalf of Covered Entity ("PHI"). The Parties are committed to complying with the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E as amended from time to time (the "Privacy Rule"), and with the Security Standards, 45 C.F.R. Part 160 and Part 164, Subpart C as amended from time to time (the "Security Rule"), under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations ("HITECH"). Business Associate acknowledges that, pursuant to HITECH, 45 C.F.R. §§ 164.308 (administrative safeguards), 164.310 (physical safeguards), 164.312 (technical safeguards), 164.316 (policies and procedures and documentation requirements) and 164.502 *et. seq.* apply to Business Associate in the same manner that such sections apply to Covered Entity. The additional requirements of Title XIII of HITECH contained in Public Law 111-005 that relate to privacy and security and that are made applicable with respect to covered entities shall also be applicable to Business Associate. The Parties are also committed to complying with the California Confidentiality of Medical Information Act, Ca. Civil Code §§ 56 *et seq.* ("CMIA"), where applicable. Business Associate acknowledges that the CMIA prohibits Business Associate from further disclosing the PHI it receives from Covered Entity where such disclosure would be violative of the CMIA. The Parties are also committed to complying with applicable requirements of the Red Flag Rules issued pursuant to the Fair and Accurate Credit Transactions Act of 2003 ("Red Flag Rules"). This Agreement sets forth the terms and conditions pursuant to which PHI, and, when applicable, Electronic Protected Health Information ("E PHI"), shall be handled. The Parties further acknowledge that state statutes or other laws or precedents may impose data breach notification or information security obligations, and it is their further intention that each shall comply with such laws to the extent such laws are applicable, as well as HITECH and HIPAA in the collection, handling, storage, and disclosure of personal data of patients or other personal identifying information exchanged or stored in connection with their relationship.

The Parties agree as follows:

1. **DEFINITIONS**

All capitalized terms used in this Agreement but not otherwise defined shall have the meaning set forth in the Privacy Rule, Security Rule and HITECH.

2. **PERMITTED USES AND DISCLOSURES OF PHI**

2.1 Unless otherwise limited herein, Business Associate may:

(a) use or disclose PHI as required by the underlying service agreement or as requested by Covered Entity to satisfy its obligations under the Privacy Rule to perform functions, activities or Services for, or on behalf of, Covered Entity from time to time, provided that such use or disclosure would not violate the Privacy or Security Rules or the standards for Business Associate Agreements set forth in 45 C.F.R. § 164.504(e), exceed the minimum necessary to accomplish the intended purpose of such use or disclosure, violate the additional requirements of HITECH contained in Public Law 111-005 that relate to privacy and security, or violate the CMIA;

(b) disclose PHI for the purposes authorized by this Agreement only: (i) to its employees, subcontractors and agents; (ii) as directed by this Agreement; or (iii) as otherwise permitted by the terms of this Agreement;

(c) use PHI in its possession to provide Data Aggregation Services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B);

(d) use PHI in its possession for proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted by 45 C.F.R. § 164.504(e)(4)(i);

(e) disclose the PHI in its possession to third parties for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate to the extent and in the manner permitted under 45 C.F.R. § 164.504(e)(4)(ii); provided that disclosures are Required by Law, or Business Associate obtains reasonable assurances from the persons to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached;

(f) use PHI to report violations of law to appropriate Federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1);

(g) de-identify any PHI obtained by Business Associate under this Agreement for use or disclosure in order to perform the underlying service agreement, or with the prior written permission of Covered Entity and such information is de-identified in accordance with 45 C.F.R. § 164.514 and 45 C.F.R. § 164.502(d)(1).

3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI

3.1 Responsibilities of Business Associate. With regard to its use and/or disclosure of PHI, Business Associate shall:

(a) use and/or disclose the PHI only as permitted or required by this Agreement or as otherwise Required by Law;

(b) report to the privacy officer of Covered Entity, in writing, (i) any use and/or disclosure of the PHI that is not permitted or required by this Agreement of which Business Associate becomes aware, and (ii) any Breach of unsecured PHI as specified by HITECH, within two (2) days of Business Associate's determination of the occurrence of such unauthorized use and/or disclosure. In such event, the Business Associate shall, in consultation with the Covered Entity, mitigate, to the extent reasonably practicable, any harmful effect that is known to the Business Associate of such improper use or disclosure. The notification of any Breach of unsecured PHI shall include, to the extent possible, the identification of each individual whose unsecured PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, used or disclosed during the Breach.

(c) use commercially reasonable safeguards to maintain the security of the PHI and to prevent use and/or disclosure of such PHI other than as provided herein;

(d) obtain and maintain an agreement with all of its subcontractors and agents that receive, use, or have access to, PHI pursuant to which agreement such subcontractors and agents

agree to adhere to the same or substantially similar restrictions and conditions on the use and/or disclosure of PHI that apply to Business Associate pursuant to this Agreement;

(e) make available all internal practices, records, books, agreements, policies and procedures and PHI relating to the use and/or disclosure of PHI to the Secretary for purposes of determining Covered Entity or Business Associate's compliance with the Privacy Rule;

document disclosures of PHI and information related to such disclosure (other than disclosures and information related to disclosures to which an exception to the accounting requirement applies under HIPAA) and, within ten (10) days of receiving a written request from Covered Entity, provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an individual for an accounting of the disclosures of the individual's PHI in accordance with 45 C.F.R. § 164.528, as well as provide an accounting of disclosures, as required by HITECH. At a minimum, the Business Associate shall provide the Covered Entity with the following information: (i) the date of the disclosure, (ii) the name of the entity or person who received the PHI, and if known, the address of such entity or person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of such disclosure which includes an explanation of the basis for such disclosure. In the event the request for an accounting is delivered directly to the Business Associate, the Business Associate shall, within two (2) days, forward such request to the Covered Entity directly. The Business Associate shall implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section;

(f) subject to Section 4.4 below, return to Covered Entity within twenty-one (21) days of the termination of this Agreement or destroy, the PHI in its possession and retain no copies, including backup copies;

(g) disclose to its subcontractors, agents or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder;

(h) if all or any portion of the PHI is maintained in a Designated Record Set:

(i) upon ten (10) days' prior written request from Covered Entity, provide access to the PHI in a Designated Record Set maintained by Business Associate, if any, to Covered Entity or, as directed by Covered Entity, to the individual to whom such PHI relates or his or her authorized representative to meet a request by such individual under 45 C.F.R. § 164.524; and

(ii) upon ten (10) days' prior written request from Covered Entity, make any amendment(s) to the PHI in a Designated Record Set maintained by Business Associate, if any, that Covered Entity directs pursuant to 45 C.F.R. § 164.526;

(i) if applicable, maintain policies and procedures to detect and prevent identity theft in connection with the provision of the Services, to the extent required to comply with the Red Flag Rules;

(j) to the extent not prohibited by law, notify the Covered Entity within five (5) days of the Business Associate's receipt of any request or subpoena for PHI. To the extent that the Covered Entity decides to assume responsibility for challenging the validity of such request, the Business Associate shall reasonably cooperate with the Covered Entity in such challenge;

(k) maintain policies and procedures that are materially in accordance with all applicable data security and privacy laws and industry standards designed to ensure the security and

integrity of the Covered Entity's data and protect against threats or hazards to such security

The Business Associate acknowledges that, as between the Business Associate and the Covered Entity, all PHI shall be and remain the sole property of the Covered Entity.

3.2 Additional Responsibilities of Business Associate with Respect to EPHI. In the event that Business Associate has access to EPHI, in addition to the other requirements set forth in this Agreement relating to PHI, Business Associate shall:

- (a) implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that Business Associate creates, receives, maintains, or transmits on behalf of Covered Entity as required by 45 C.F.R. Part 164, Subpart C;
- (b) ensure that any subcontractor or agent to whom Business Associate provides any EPHI agrees in writing to implement reasonable and appropriate safeguards to protect such EPHI; and
- (c) report to the privacy officer of Covered Entity, in writing, any Security Incident involving EPHI of which Business Associate becomes aware within two (2) days of Business Associate's discovery of such Security Incident. For purposes of this Section, a Security Incident shall mean (consistent with the definition set forth at 45 C.F.R. § 164.304), the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with systems operations in an information system. In such event, the Business Associate shall, in consultation with the Covered Entity, mitigate, to the extent reasonably practicable, any harmful effect that is known to the Business Associate of such improper use or disclosure. The parties acknowledge and agree that this section constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence of attempted but Unsuccessful Security Incidents (as defined below) for which no additional notice to Covered Entity shall be required. "Unsuccessful Security Incidents" shall include, but not be limited to, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denials of service and any combination of the above, so long as no such incident results in the unauthorized access, use or disclosure of PHI.

3.3 Responsibilities of Covered Entity. Covered Entity shall, with respect to Business Associate:

- (a) provide Business Associate a copy of Covered Entity's notice of privacy practices ("Notice") currently in use;
- (b) notify Business Associate of any limitations in the Notice pursuant to 45 C.F.R. § 164.520, to the extent that such limitations may affect Business Associate's use or disclosure of PHI;
- (c) notify Business Associate of any changes to the Notice that Covered Entity provides to individuals pursuant to 45 C.F.R. § 164.520, to the extent that such changes may affect Business Associate's use or disclosure of PHI;
- (d) notify Business Associate of any changes in, or withdrawal of, the consent or authorization of an individual regarding the use or disclosure of PHI provided to Covered Entity pursuant to 45 C.F.R. § 164.506 or § 164.508, to the extent that such changes may affect Business Associate's use or disclosure of PHI; and

- (e) notify Business Associate, in writing and in a timely manner, of any restrictions on

use and/or disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by Covered Entity, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

(f) Covered Entity shall not cause Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done directly by Covered Entity.

(g) Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, such PHI is the minimum necessary PHI for the accomplishment of Business Associate's purpose.

(h) Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, Covered Entity has obtained the consents, authorizations and/or other forms of legal permission required under HIPAA and other applicable law.

4. TERMS AND TERMINATION

4.1 Term. This Agreement shall become effective on the Effective Date and shall continue in effect unless terminated as provided in this Article 4. Certain provisions and requirements of this Agreement shall survive its expiration or other termination as set forth in Section 5.1 herein.

4.2 Termination. Either Covered Entity or Business Associate may terminate this Agreement and any related agreements if the terminating Party determines in good faith that the terminated Party has breached a material term of this Agreement; provided, however, that no Party may terminate this Agreement if the breaching Party cures such breach to the reasonable satisfaction of the terminating Party within thirty (30) days after the breaching Party's receipt of written notice of such breach.

4.3 Automatic Termination. This Agreement shall automatically terminate without any further action of the Parties upon the termination or expiration of Business Associate's provision of Services to Covered Entity.

4.4 Effect of Termination. Upon termination or expiration of this Agreement for any reason, Business Associate shall return or destroy all PHI pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(I) if, and to the extent that, it is feasible to do so. Business Associate shall require the same of its subcontractors or agents. To the extent it is not feasible for Business Associate to return or destroy any portion of the PHI, upon request from Covered Entity, Business Associate shall provide Covered Entity a statement that Business Associate has determined that it is infeasible to return or destroy all or some portion of the PHI in its possession or in possession of its subcontractors or agents. Business Associate shall extend any and all protections, limitations and restrictions contained in this Agreement to any PHI retained after the termination of this Agreement until such time as the PHI is returned to Covered Entity or destroyed, and Business Associate shall require its subcontractors or agents to do the same.

5. MISCELLANEOUS

5.1 Survival. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 4.4, 5.1, 5.6, and 5.7, and Section 2.1 (solely with respect to PHI that Business Associate retains in accordance with Section 4.4 because it is not feasible to return or destroy such PHI), shall survive termination of this Agreement until such time as the PHI is returned to Covered Entity or destroyed. In addition, Section 3.1(i) shall survive termination of this Agreement, provided that Covered Entity determines that the PHI being retained pursuant to Section 4.4 constitutes a Designated Record Set.

5.2 Amendments; Waiver. This Agreement may not be modified or amended, except in a writing duly signed by authorized representatives of the Parties. To the extent that any relevant provision of the HIPAA, HITECH or Red Flag Rules is materially amended in a manner that changes the obligations of Business Associates or Covered Entities, the Parties agree to negotiate in good faith

appropriate amendment(s) to this Agreement to give effect to the revised obligations. Further, no provision of this Agreement shall be waived, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

5.3 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

5.4 Notices. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below, and/or via facsimile to the facsimile telephone numbers listed below.

If to Business Associate, to:

Brainlab, Inc.
3 Westbrook Corporate Center, Suite 400
Westchester, IL 60154

Attn: President
With a copy to Corporate Counsel

Phone: 708 409 1343

If to Covered Entity, to:

Attn: _____
Phone: _____
Fax: _____

Each Party named above may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided. Such notice is effective upon receipt of notice, but receipt is deemed to occur on next business day if notice is sent by FedEx or other overnight delivery service.

5.5 Counterparts; Facsimiles, .pdf. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.

5.6 Choice of Law; Interpretation. This Agreement shall be governed by the laws of the State of California; as provided, however, that any ambiguities in this Agreement shall be resolved in a manner that allows Business Associate to comply with the Privacy Rule, and, if applicable, the Security Rule and the CMIA.

5.7 Indemnification. Intentionally omitted.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf as of the Effective Date.

[BUSINESS ASSOCIATE]

**COUNTY OF MONTEREY, ON BEHALF OF
NATIVIDAD MEDICAL CENTER**

By: 

By: _____

Print Name: SEAN M. CLARK

Print Name: _____

Print Title: PRESIDENT

Print Title: _____

Date: 16 APR 15

Date: _____

