

BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (the “**Agreement**”) is entered into between [REDACTED] (“**Covered Entity**”), and Centering Healthcare Institute, a 501c3 non-profit based in Boston, MA (“**Business Associate**”), which shall be deemed effective [REDACTED] (the “**Effective Date**”).

WHEREAS, the U.S. Department of Health and Human Services issued regulations on “Standards for Privacy of Individually Identifiable Health Information” comprising 45 C.F.R. Parts 160 and 164, Subparts A and E (the “**Privacy Standards**”), “Security Standards for the Protection of Electronic Protected Health Information” comprising 45 C.F.R. Parts 160 and 164, Subpart C (the “**Security Standards**”), “Standards for Notification in the Case of Breach of Unsecured Protected Health Information” comprising 45 C.F.R. Parts 160 and 164, Subpart D (the “**Breach Notification Standards**”), and “Rules for Compliance and Investigations, Impositions of Civil Monetary Penalties, and Procedures for Hearings” comprising 45 C.F.R. Part 160, Subparts C, D, and E (“the “**Enforcement Rule**”) promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”), the Health Information Technology for Economic and Clinical Health Act (“**HITECH Act**”), and the Genetic Information and Nondiscrimination Act of 2008 (“**GINA**”) (the Privacy Standards, the Security Standards, the Breach Notification Standards, and the Enforcement Rule are collectively referred to herein as the “**HIPAA Standards**”).

WHEREAS, in conformity with the HIPAA Standards, Business Associate has, and/or will create, receive, maintain, or transmit certain Protected Health Information (“**PHI**”) pursuant to the services provided under the Centering Master Site License Agreement (the “**Service Agreement**”).

WHEREAS, Covered Entity is required by the HIPAA Standards to obtain satisfactory assurances that Business Associate will appropriately safeguard all PHI created, received, maintained, or transmitted by Business Associate on behalf of Covered Entity.

WHEREAS, the parties hereto desire to enter into this Agreement to memorialize their obligations with respect to PHI pursuant to the requirements of the HIPAA Standards.

NOW, THEREFORE, Covered Entity and Business Associate agree as follows:

Section 1. Definitions. Except as otherwise specified herein, capitalized terms used but not defined in this Agreement shall have the same meaning as those terms in 45 C.F.R. Parts 160 and 164.

- (a) **Breach**, as used in Section 2 of this Agreement, means the unauthorized acquisition, access, use, or disclosure of PHI which compromises the security or privacy of such information.
- (b) **C.F.R.** means the Code of Federal Regulations.
- (c) **ePHI** means any PHI that is received, maintained, transmitted or utilized for any purpose in electronic form by Business Associate on behalf of Covered Entity.

- (d) GINA means the Genetic Information and Nondiscrimination Act of 2008 (P.L. 110-233) and the regulations promulgated thereunder.
- (e) HIPAA means the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-91) and any successor statutes, rules and regulations.
- (f) HITECH Act means the American Recovery and Reinvestment Act of 2009 (P.L. 111-5), Div. A, Title XIII and Div. B, Title IV, the Health Information Technology for Economic and Clinical Health Act and the regulations promulgated thereunder.
- (g) Individual has the same meaning as the term “individual” in 45 C.F.R. § 160.103 and shall include a person who qualifies as personal representative in accordance with 45 C.F.R. § 164.502(g).
- (h) Protected Health Information (“**PHI**”) has the same meaning as the term “protected health information” as defined in 45 C.F.R. § 160.103, which generally includes all Individually Identifiable Health Information regardless of form; limited, however, to the information that Business Associate creates, receives, maintains, or transmits on behalf of Covered Entity. PHI excludes Individually Identifiable Health Information regarding a person who has been deceased for more than fifty (50) years.
- (i) Required by Law has the same meaning as the term “required by law” in 45 C.F.R. § 164.103.
- (j) Secretary means the Secretary of the United States Department of Health and Human Services or his/her designee.
- (k) Security Incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

Section 2. Obligations and Activities of Business Associate.

- (a) Business Associate agrees to not use or further disclose PHI other than as permitted or required by this Agreement or as Required by Law. Business Associate shall also comply with any further limitations on uses and disclosures of PHI by Covered Entity in accordance with 45 C.F.R. § 164.522, provided that Covered Entity communicates such limitations to Business Associate.
- (b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.
- (c) Business Associate shall use appropriate safeguards and comply with 45 C.F.R. Part 164, Subpart C with respect to ePHI that it creates, receives, maintains or transmits on behalf of Covered Entity.

- (d) Business Associate agrees to report to Covered Entity any use or disclosure of PHI not provided for by this Agreement of which Business Associate becomes aware. Additionally, Business Associate shall report immediately to Covered Entity any Security Incident of which Business Associate becomes aware. At the request of Covered Entity, Business Associate shall identify the date, nature, and scope of the Security Incident, Business Associate's response to the Security Incident, and the identification of the party responsible for causing the Security Incident, if known. Notwithstanding the foregoing, the parties acknowledge and agree that this Section 3(d) constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Covered Entity shall be required. Unsuccessful Security Incidents means, without limitation, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of Covered Entity's electronic PHI.
- (e) Business Associate shall notify Covered Entity upon discovery of any Breach of Unsecured Protected Health Information. Without undue delay and within thirty (30) days of the date Business Associate discovers the Breach, Business Associate shall provide such information to Covered Entity as required by the Breach Notification Standards.
- (f) Business Associate shall obtain and maintain an agreement with each agent or subcontractor that creates, receives, maintains, or transmits Covered Entity's PHI on behalf of Business Associate. Under the agreement, such agent or subcontractor shall agree to the same restrictions and conditions that apply to Business Associate pursuant to this Agreement with respect to such PHI.
- (g) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement or the HIPAA Standards.
- (h) Upon request of Covered Entity, Business Associate agrees to provide access to PHI in a Designated Record Set, as defined in 45 C.F.R. § 164.501, to an Individual in order for Covered Entity to comply with the requirements under 45 C.F.R. § 164.524. Further, if the PHI that is the subject of a request for access is maintained in one or more Designated Record Sets electronically and if the Individual requests an electronic copy of such information, Business Associate shall provide access to the PHI in the electronic form and format requested, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by Covered Entity and the Individual. Business Associate further agrees to make available PHI for amendment and incorporate any amendments to PHI in a Designated Record Set in order for Covered Entity to comply with 45 C.F.R. § 164.526. If Business Associate provides copies or summaries of PHI to an Individual, it may impose a reasonable, cost-based fee in accordance with 45 C.F.R. § 164.524(c)(4), provided that the fee includes only the cost of labor for copying

the PHI requested by the Individual, whether in paper or electronic form, and supplies for creating the paper copy or electronic media if the Individual requests that the electronic copy be provided on portable media.

- (i) Business Associate agrees to make its internal practices, books, and records, including policies and procedures relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Secretary of the U.S. Department of Health and Human Services determining Covered Entity's compliance with the Privacy Standards.
- (j) Business Associate agrees to document and make available information required to respond to provide an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528 and the HITECH Act. Business Associate further agrees to provide Covered Entity such information upon request to permit 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 and the HITECH Act.
- (k) Business Associate acknowledges that it will make reasonable efforts to limit the use or disclosure of PHI to perform or fulfill a function required or permitted under this Agreement to the minimum necessary to accomplish the intended purpose of such use or disclosure, as specified by the HIPAA Standards and any relevant guidance issued by the U.S. Department of Health and Human Services.
- (l) In the event that Business Associate agrees to carry out an obligation of Covered Entity under 45 C.F.R. Part 164, Subpart E, Business Associate agrees to comply with the requirements of 45 C.F.R. Part 164, Subpart E that apply to Covered Entity in the performance of such obligations.

Section 3. Permitted Uses and Disclosures of PHI by Business Associate.

- (a) General Use and Disclosure Provisions. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity pursuant to the Service Agreement between the parties, provided that such use or disclosure would not violate the Privacy Standards if done by Covered Entity.
- (b) Specific Use and Disclosure Provisions.
 - (1) Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of Business Associate, or to carry out the legal responsibilities of Business Associate. Except as otherwise limited in this Agreement, Business Associate may disclose PHI (i) for the proper management and administration of Business Associate, or (ii) to carry out Business Associate's legal responsibilities if (a) the disclosure is Required by Law, or (b) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information 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 Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

- (2) Business Associate may use and further disclose PHI to provide Data Aggregation services as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
- (3) Business Associate may use PHI to de-identify PHI in accordance with 45 C.F.R. § 164.502(d).

Section 4. Term and Termination.

- (a) Term. The provisions of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with the provisions of this Section, shall continue in full force and effect until terminated in accordance with the terms hereof or the terms of the Services Agreement.
- (b) Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity will provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within a reasonable period of time, Covered Entity may terminate this Agreement. If cure is not possible, Covered Entity may immediately terminate this Agreement.
- (c) Effect of Termination.
 - (1) Except as provided in paragraph (2) of this Section 4(c), upon termination of this Agreement for any reason, Business Associate shall return or destroy all PHI received from, or created or received by Business Associate on behalf of, Covered Entity that Business Associate maintains in any form.
 - (2) In the event that Business Associate reasonably believes that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon providing such notice, Business Associate shall extend the protections of this Agreement 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.

Section 5. Notices. Any notices or communications to be given pursuant to this Agreement shall be made to the addresses given below:

<p>If to Business Associate, to:</p> <p>Legal Department</p> <p>Centering Healthcare Institute</p> <p>89 South St., Ste. LL-02,</p> <p>Boston MA 02111</p>	<p>If to Covered Entity, to:</p>

Section 6. Miscellaneous.

- (a) Regulatory References. A reference in this Agreement to a section in the HIPAA Standards means the section then in effect.
- (b) Amendment. The parties agree to take such action as may be necessary to amend this Agreement from time to time to ensure the parties comply with the requirements of the HIPAA Standards and any other applicable law or regulation. Any amendment to this Agreement proposed by either party shall not be effective unless mutually agreed to in writing by both parties.
- (c) Interpretation. Any ambiguity in this Agreement shall be resolved to permit the parties to comply with the HIPAA Standards. In the event of any inconsistency or conflict between this Agreement and the Service Agreement, the terms and conditions of this Agreement shall govern and control.
- (d) No Third Party Beneficiary. Nothing express or implied in this Agreement or in the Service 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.
- (e) Governing Law. This Agreement shall be governed by and construed in accordance with the same internal laws as that of the Service Agreement.
- (f) Multiple Counterparts. This Agreement may be executed in multiple counterparts all of which shall be considered an original Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

COVERED ENTITY	BUSINESS ASSOCIATE
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

SAMPLE