

[Company Name]

**Business Associate Agreement**

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This Business Associate Agreement (“Agreement”), effective \_\_\_\_\_, 200\_ (the “Effective Date”), is entered into by and between \_\_\_\_\_ (the “Business Associate”) and [Company Name] (the “Covered Entity”), with an address at [Company Address], [Company City] [Company State] [Company Zip] (each a “Party” and collectively the “Parties”).

The Business Associate is a \_\_\_\_\_ and the Covered Entity is a [Company Type] providing healthcare services. The Parties have a prior \_\_\_\_\_ Agreement dated \_\_\_\_\_ (the " \_\_\_\_\_ Agreement") under which the Business Associate regularly uses and/or discloses Protected Health Information (“PHI”) in its performance of the Services described below. Both Parties are committed to complying with the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Regulation”) under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). This Agreement sets forth the terms and conditions pursuant to which PHI that is provided by, or created or received by, the Business Associate from or on behalf of the Covered Entity, will be handled between the Business Associate and the Covered Entity and with third parties during the term of their \_\_\_\_\_ Agreement and after its termination. The Parties hereby agree as follows:

**1. DEFINITIONS.**

1.1 Health Care Operations. Health Care Operations shall have the meaning set out in its definition at 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.2 Privacy Officer. Privacy Officer shall have the meaning as set out in its definition at 45 C.F.R. § 164.530(a)(1) as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.3 Security Officer. Security Officer shall have the meaning as set out in its definition at 45 C.F.R. § 164.308(a)(2) as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.4 Protected Health Information (PHI). "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR 164.501 and 45 CFR 160.103, including Electronic Protected Health Information, limited to the information created, received, maintained or transmitted by Business Associate from or on behalf of Covered Entity.

1.5 Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

1.6 Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

1.6 Security Rule. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR part 160 and part 164, subpart C.

1.6 Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.

1.7 Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

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

2.1 Services. Pursuant to the \_\_\_\_\_ Agreement, Business Associate provides services described therein ("Services") for the Covered Entity that involve the use and disclosure of PHI. Except as otherwise specified herein, the Business Associate may make any and all uses of PHI necessary to perform its obligations under the \_\_\_\_\_ Agreement. All other uses not authorized by this Agreement are prohibited. Business Associate may disclose PHI for the purposes authorized by this Agreement only, (i) to its employees, subcontractors and agents, in accordance with Section 3.1(e), (ii) as directed by the Covered Entity, or (iii) as otherwise permitted by the terms of this Agreement.

## **3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI**

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

- a. use and/or disclose the PHI only as permitted or required by this Agreement or as otherwise required by law.
- b. use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c. report to the designated Privacy Officer of the Covered Entity, in writing, any use and/or disclosure of the PHI that is not permitted or required by this Agreement of which Business Associate becomes aware within 15 days of the Business Associate's discovery of such unauthorized use and/or disclosure.
- d. implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Electronic Protected Health Information that it creates, receives, maintains or transmits on behalf of the covered entity.
- e. report to the designated Security Officer of the Covered Entity, in writing, of any security incident of which it becomes aware.
- f. establish procedures for mitigating, to the greatest extent possible, any deleterious effects from any improper use and/or disclosure of PHI that the Business Associate reports to the Covered Entity.

- e. require all of its subcontractors and agents that receive or use, or have access to, PHI under this Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of PHI that apply to the Business Associate pursuant to section 3 of this Agreement.
- g. agree to provide access, at the request of Covered Entity, to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.
- h. agree to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or an Individual, and in the time and manner.
- i. agree to make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available, to the Covered Entity, or to the Secretary, in a time and manner negotiated or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule, subject to attorney-client and other applicable legal privileges.
- j. agree to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.
- k. within 45 days of receiving a written request from the Covered Entity, provide to the Covered Entity such information as is requested by the Covered Entity to permit the 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.
- l. subject to Section 4.3 below, return to the Covered Entity or destroy, within 30 days of the termination of this Agreement, the PHI in its possession and retain no copies (which for purposes of this Agreement shall mean destroy all backup tapes).
- m. disclose to its subcontractors, agents or other third parties, and request from the Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder.
- n. authorize the termination of the \_\_\_\_\_ Agreement by the Covered Entity, if the Covered Entity determines that the Business Associate has violated a material term of this Agreement.

### **3.2 Specific Use and Disclosure Provisions**

- a. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- b. Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or Business

Associate obtains reasonable assurances from the person 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.

c. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).

d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with Sec. 164.502(j)(1).

3.3 Responsibilities of the Covered Entity. With regard to the use and/or disclosure of PHI by the Business Associate, the Covered Entity hereby agrees:

a. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.

b. to inform the Business Associate of any changes in the form of notice of privacy practices (the "Notice") that the Covered Entity provides to individuals pursuant to 45 C.F.R. §164.520, and provide the Business Associate a copy of the Notice currently in use.

c. to notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.

d. to not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

e. to inform the Business Associate of any changes in, or withdrawal of, the consent or authorization provided to the Covered Entity by individuals pursuant to 45 C.F.R. §164.506 or §164.508.

f. to inform the Business Associate of any opt-outs exercised by any individual from marketing and/or fundraising activities of the Covered Entity pursuant to 45 C.F.R. § 164.514(e).

g. to notify the Business Associate, in writing and in a timely manner, of any arrangements permitted or required of the Covered Entity under 45 C.F.R. part 160 and 164 that may impact in any manner the use and/or disclosure of PHI by the Business Associate under this Agreement, including, but not limited to, restrictions on use and/or disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by the Covered Entity.

h. that Business Associate may make any use and/or disclosure of PHI permitted under 45 C.F.R. § 164.512 except uses or disclosure for research are not permitted without prior approval by the covered entity.

#### **4. REPRESENTATIONS AND WARRANTIES**

4.1 Mutual Representations and Warranties of the Parties. Each Party represents and warrants to the other Party:

a. that it is duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized or licensed, it has the full power to enter into this Agreement and to perform its obligations hereunder, and that the performance by it of its obligations under this Agreement have been duly authorized by all necessary corporate or other actions and will not violate any provision of any license, corporate charter or bylaws.

b. that neither the execution of this Agreement, nor its performance hereunder, will directly or indirectly violate or interfere with the terms of another agreement to which it is a party, or give any governmental entity the right to suspend, terminate, or modify any of its governmental authorizations or assets required for its performance hereunder. Each Party represents and warrants to the other Party that it will not enter into any agreement the execution and/or performance of which would violate or interfere with this Agreement.

c. that it is not currently the subject of a voluntary or involuntary petition in bankruptcy, does not currently contemplate filing any such voluntary petition, and is not aware of any claim for the filing of an involuntary petition.

d. that all of its employees, agents, representatives and members of its workforce, whose services may be used to fulfill obligations under this Agreement are or shall be appropriately informed of the terms of this Agreement and are under legal obligation to each Party, respectively, by contract or otherwise, sufficient to enable each Party to fully comply with all provisions of this Agreement including, without limitation, the requirement that modifications or limitations that the Covered Entity has agreed to adhere to with regards to the use and disclosure of PHI of any individual that materially affects and/or limits the uses and disclosures that are otherwise permitted under the Standard will be communicated to the Business Associate, in writing, and in a timely fashion.

e. that it will reasonably cooperate with the other Party in the performance of the mutual obligations under this Agreement.

f. that neither the Party, nor its shareholders, members, directors, officers, agents, employees or members of its workforce have been excluded or served a notice of exclusion or have been served with a notice of proposed exclusion, or have committed any acts which are cause for exclusion, from participation in, or had any sanctions, or civil or criminal penalties imposed under, any federal or state healthcare program, including but not limited to Medicare or Medicaid, or have been convicted, under federal or state law (including without limitation a plea of nolo contendere or participation in a first offender deterred adjudication or other arrangement whereby a judgment of conviction has been withheld), of a criminal offense related to (a) the neglect or abuse of a patient, (b) the delivery of an item or service, including the performance of management or administrative services related to the delivery of an item or service, under a federal or state healthcare program, (c) fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in any program operated by or financed in whole or in part by any federal, state or local government agency, (d) the unlawful, manufacture, distribution, prescription or dispensing of a controlled substance, or (e) interference with or obstruction of any

investigation into any criminal offense described in (a) through (d) above. Each Party further agrees to notify the other Party immediately after the Party becomes aware that any of the foregoing representation and warranties may be inaccurate or may become incorrect.

## **5. TERMS AND TERMINATION**

5.1 Term. This Agreement shall become effective on the Effective Date and shall continue in effect until all obligations of the Parties have been met, unless terminated as provided in this Section 5. In addition, certain provisions and requirements of this Agreement shall survive its expiration or other termination in accordance with Section 8.3 herein.

5.2 Termination by the Covered Entity. As provided for under 45 C.F.R. § 164.504(e)(2)(iii), the Covered Entity may immediately terminate this Agreement and any related agreements if the Covered Entity makes the determination that the Business Associate has breached a material term of this Agreement. Alternatively, the Covered Entity may choose to: (i) provide the Business Associate with 30 days written notice of the existence of an alleged material breach; and (ii) afford the Business Associate an opportunity to cure said alleged material breach upon mutually agreeable terms. In the event that mutually agreeable terms cannot be achieved within 45 days, Business Associate must cure said breach to the satisfaction of the Covered Entity within 60 days. Failure to cure in the manner set forth in this paragraph is grounds for the immediate termination of this Agreement.

5.3 If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary.

5.4 Termination by Business Associate. If the Business Associate makes the determination that a material condition of performance has changed under the \_\_\_\_\_ Agreement or this Agreement, or that the Covered Entity has breached a material term of this Agreement, Business Associate may provide thirty (30) days notice of its intention to terminate this Agreement. Business Associate agrees, however, to cooperate with Covered Entity to find a mutually satisfactory resolution to the matter prior to terminating and further agrees that, notwithstanding this provision, it shall not terminate this Agreement so long as the \_\_\_\_\_ Agreement is in effect.

5.5 Automatic Termination. This Agreement will automatically terminate without any further action of the Parties upon the termination or expiration of the \_\_\_\_\_ Agreement dated \_\_\_\_\_ between the Parties.

5.6 Effect of Termination. Upon the event of termination pursuant to this Section 5, Business Associate agrees to return or destroy all PHI pursuant to 45 C.F.R. § 164.504(e)(2)(I), if it is feasible to do so. Prior to doing so, the Business Associate further agrees to recover any PHI in the possession of its subcontractors or agents. If it is not feasible for the Business Associate to return or destroy said PHI, the Business Associate will notify the Covered Entity in writing. Said notification shall include: (i) a statement that the Business Associate has determined that it is infeasible to return or destroy the PHI in its possession, and (ii) the specific reasons for such determination. Business Associate further agrees to extend any and all protections, limitations and restrictions contained in this Agreement to the Business Associate's use and/or disclosure of any PHI retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the PHI infeasible. If it is infeasible for the Business Associate to obtain, from a subcontractor or agent any PHI in the possession of the subcontractor or agent, the Business Associate must provide a written

explanation to the Covered Entity and require the subcontractors and agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the subcontractors' and/or agents' use and/or disclosure of any PHI retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the PHI infeasible.

## **6. CONFIDENTIALITY**

6.1 Confidentiality Obligations. In the course of performing under this Agreement, each Party may receive, be exposed to or acquire Confidential Information, including but not limited to, all information, data, reports, records, summaries, tables and studies, whether written or oral, fixed in hard copy or contained in any computer data base or computer readable form, as well as any information identified as confidential ("Confidential Information") of the other Party. For purposes of this Agreement, "Confidential Information" shall not include PHI, the security of which is the subject of this Agreement and is provided for elsewhere. The Parties including their employees, agents or representatives: (i) shall not disclose to any third party the Confidential Information of the other Party except as otherwise permitted by this Agreement; (ii) only permit use of such Confidential Information by employees, agents and representatives having a need to know in connection with performance under this Agreement; and (iii) advise each of their employees, agents, and representatives of their obligations to keep such Confidential Information confidential. Notwithstanding anything to the contrary herein, each Party shall be free to use, for its own business purposes, any ideas, suggestions, concepts, know-how or techniques contained in information received from each other that directly relates to the performance under this Agreement. This provision shall not apply to Confidential Information: (a) after it becomes publicly available through no fault of either Party; (b) which is later publicly released by either Party in writing; (c) which is lawfully obtained from third parties without restriction; or (d) which can be shown to be previously known or developed by either Party independently of the other Party.

## **7. INDEMNIFICATION**

7.1 Indemnification. The Parties agree to indemnify, defend and hold harmless each other and each other's respective employees, directors, officers, subcontractors, agents or other members of its workforce, each of the foregoing hereinafter referred to as "indemnified party," against all actual and direct losses suffered by the indemnified party and all liability to third parties arising from or in connection with any breach of this Agreement or of any warranty hereunder or from any negligence or wrongful acts or omissions, including failure to perform its obligations under the Privacy Regulation, by the indemnifying party or its employees, directors, officers, subcontractors, agents or other members of its workforce. Accordingly, on demand, the indemnifying party shall reimburse any indemnified party for any and all actual and direct losses, liabilities, lost profits, fines, penalties, costs or expenses (including reasonable attorneys' fees) which may for any reason be imposed upon any indemnified party by reason of any suit, claim, action, proceeding or demand by any third party which results from the indemnifying party's breach hereunder. The Parties' obligation to indemnify any indemnified party shall survive the expiration or termination of this Agreement for any reason.

## **8. MISCELLANEOUS**

8.1 Covered Entity. For purposes of this Agreement, Covered Entity shall include all entities covered by the joint notice of information practices (or privacy notice), which includes Test Company.

8.2 Business Associate. For purposes of this Agreement, Business Associate shall include the named Business Associate herein. However, in the event that the Business Associate is otherwise a covered entity under the Privacy Regulation, that entity may appropriately designate a health care component of the entity, pursuant to 45 C.F.R. § 164.504(a), as the Business Associate for purposes of this Agreement.

8.3 Survival. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 5.6, 8.5, 8.9, 9.0 and Section 3.1 solely with respect to PHI Business Associate retains in accordance with Section 5.6 because it is not feasible to return or destroy such PHI, shall survive termination of this Agreement indefinitely.

8.4 Amendments; Waiver. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191. This Agreement may not be modified, nor shall any provision hereof be waived or amended, 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.

8.5 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.

8.6 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 (other than for the delivery of fees) via facsimile to the facsimile telephone numbers listed below.

If to Business Associate, to:

\_\_\_\_\_  
\_\_\_\_\_  
Attention: \_\_\_\_\_  
Fax: \_\_\_\_\_

with a copy (which shall not constitute notice) to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Attn: \_\_\_\_\_  
Fax: \_\_\_\_\_

If to Covered Entity, to:

[Company Name]  
[Company Address], [Company City] [Company State] [Company Zip]  
Attention: Privacy Officer  
Fax: [Company Fax]

with a copy (which shall not constitute notice) to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Attn: \_\_\_\_\_

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 herein above provided.

8.7 Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

8.8 Counterparts; Facsimiles. 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.

8.9 Disputes. If any controversy, dispute or claim arises between the Parties with respect to this Agreement, the Parties shall make good faith efforts to resolve such matters informally.

9.0 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf effective as of \_\_\_\_\_, 200\_.

**COVERED ENTITY**

**BUSINESS ASSOCIATE**

By: \_\_\_\_\_

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Title: \_\_\_\_\_

Print Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_