

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the “Agreement”) is made by and between Montgomery County, Maryland (hereinafter referred to as “Covered Entity”), and _____ (hereinafter referred to as “Business Associate”). Covered Entity and Business Associate shall collectively be known herein as the “Parties.”

I. GENERAL

A. Covered Entity has a business relationship with Business Associate that is memorialized in Montgomery County Contract # _____ (the “Underlying Agreement”), pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996, including all pertinent regulations (45 CFR Parts 160 and 164), issued by the U.S. Department of Health and Human Services, including Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as codified in Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), and including any and all applicable Privacy, Security, Enforcement, or Notice (Breach Notification) Rules or requirements (collectively, “HIPAA”), as all are amended from time to time; and

B. The performance of the Underlying Agreement may involve the creation, exchange, or maintenance of Protected Health Information (“PHI”) as that term is defined under HIPAA; and

C. For good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this Agreement for the purpose of ensuring compliance with the requirements of HIPAA; and

D. This Agreement articulates the obligations of the Parties as to use and disclosure of PHI. It does not affect Business Associate’s obligations to comply with the the Maryland Confidentiality of Medical Records Act (Md. Code Ann., Health-General I §§4-301 *et seq.*) (“MCMRA”) or other applicable law with respect to any information the County may disclose to Business Associate as part of Business Associate’s performance of the Underlying Agreement; and

E. This Agreement supersedes and replaces any and all Business Associate Agreements the Covered Entity and Business Associate may have entered into prior to the date hereof; and

F. The above premises having been considered and incorporated by reference into the sections below, the Parties, intending to be legally bound, agree as follows:

II. DEFINITIONS.

A. The terms used in this Agreement have the same meaning as the definitions of those terms in HIPAA. In the absence of a definition in HIPAA, the terms have their commonly understood meaning.

B. Consistent with HIPAA, and for ease of reference, the Parties expressly note the definitions of the following terms:

1. "Breach" is defined at 45 CFR § 164.402.
2. "Business Associate" is defined at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean _____.
3. "Covered Entity" is defined at 45 CFR § 160.103, and in reference to the party to this Agreement, shall mean the County.
4. "Designated Record Set" is defined at 45 CFR §164.501.
5. "Individual" is defined at 45 CFR §§ 160.103, 164.501 and 164.502(g), and includes a person who qualifies as a personal representative.
6. "Protected Health Information" or "PHI" is defined at 45 CFR § 160.103.
7. "Required By Law" is defined at 45 CFR § 164.103.
8. "Secretary" means the Secretary of the U.S. Department of Health and Human Services or designee.
9. "Security Incident" is defined at 45 CFR § 164.304.
10. "Unsecured Protected Health Information" or "Unsecured PHI" means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology, as specified by the Secretary in the guidance as noted under the HITECH Act, section 13402(h)(1) and (2) of Public Law 111-5, codified at 42 U.S.C. § 17932(h)(1) and (2), and as specified by the Secretary in 45 CFR 164.402.

III. PERMISSIBLE USE AND DISCLOSURE OF PHI

A. Except as otherwise limited in this Agreement, or by privilege, protection, or confidentiality under HIPAA, MCMRA, or other applicable law, Business Associate may use or disclose (including permitting acquisition or access to) PHI to perform applicable functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement. Moreover, the provisions of HIPAA are expressly incorporated by reference into, and made a part of, this Agreement.

B. Business Associate may use or disclose (including permitting acquisition or access to) PHI only as permitted or required by this Agreement or as Required By Law.

C. Business Associate is directly responsible for full compliance with the relevant requirements of HIPAA.

D. Business Associate must not use or disclose (including permitting acquisition or access to) PHI other than as permitted or required by this Agreement or HIPAA, and must use or disclose PHI only in a manner consistent with HIPAA. As part of this, Business Associate must use appropriate safeguards to prevent use or disclosure of PHI that is not permitted by this Agreement or HIPAA. Furthermore, Business Associate must take reasonable precautions to protect PHI from loss, misuse, and unauthorized access, disclosure, alteration, and destruction.

E. Business Associate must implement and comply with administrative, physical, and technical safeguards governing the PHI, in a manner consistent with HIPAA, 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.

F. Business Associate must immediately notify Covered Entity, in a manner consistent with HIPAA, of: (i) any use or disclosure of PHI not provided for by this Agreement, including a Breach of PHI of which it knows or by exercise of reasonable diligence would have known, as required at 45 CFR §164.410; and, (ii) any Security Incident of which it becomes aware as required at 45 CFR §164.314(a)(2)(i)(C). Business Associate's notification to Covered Entity required by HIPAA and this Section III.F must:

1. Be made to Covered Entity without unreasonable delay and in no case later than 14 calendar days after Business Associate: a) knows, or by exercising reasonable diligence would have known, of a Breach, b) becomes aware of a Security Incident, or c) becomes aware of any use or disclosure of PHI not provided for by this Agreement;

2. Include the names and addresses of the Individual(s) whose PHI is the subject of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement. In addition, Business Associate must provide any additional information reasonably requested by Covered Entity for purposes of investigating the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

3. Be in substantially the same form as Exhibit A hereto;

4. Include a brief description of what happened, including the date of the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, if known, and the date of the discovery of the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

5. Include a description of the type(s) of Unsecured PHI that was involved in the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement (such as full name, Social Security number, date of birth, home address, account number, disability code, or other types of information that were involved);

6. Identify the nature and extent of the PHI involved, including the type(s) of identifiers and the likelihood of re identification;

7. If known, identify the unauthorized person who used or accessed the PHI or to whom the disclosure was made;

8. Articulate any steps the affected Individual(s) should take to protect him or herself from potential harm resulting from the Breach, Security Incident, or use or disclosure of PHI not permitted by this Agreement;

9. State whether the PHI was actually acquired or viewed;

10. Provide a brief description of what the Covered Entity and the Business Associate are doing to investigate the Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, to mitigate losses, and to protect against any further Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement;

11. Note contact information and procedures for an Individual(s) to ask questions or learn additional information, which must include a toll-free telephone number of Business Associate, along with an e-mail address, Web site, or postal address;

and

12. Include a draft letter for the Covered Entity to utilize, in the event Covered Entity elects, in its sole discretion, to notify the Individual(s) that his or her PHI is the subject of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement that includes the information noted in Section III.F.4 – III.F.11 above.

G. Business Associate must, and is expected to, directly and independently fulfill all notification requirements under HIPAA.

H. In the event of a Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement, Business Associate must mitigate, to the extent practicable, any harmful effects of said disclosure that are known to it.

I. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), Business Associate agrees to ensure that any agent, subcontractor, or employee to whom it provides PHI (received from, or created or received by, Business Associate on behalf of Covered Entity) agrees to the same restrictions, conditions, and requirements that apply through this Agreement to Business Associate with respect to such information.

J. Business Associate must ensure that any contract or other arrangement with a subcontractor meets the requirements of paragraphs 45 CFR §164.314(a)(2)(i) and (a)(2)(ii) required by 45 CFR § 164.308(b)(3) between a Business Associate and a subcontractor, in the same manner as such requirements apply to contracts or other arrangements between a Covered Entity and Business Associate.

K. Pursuant to 45 CFR § 164.502(a)(4)(ii), Business Associate must disclose PHI to the Covered Entity, Individual, or Individual's designee, as necessary to satisfy a Covered

Entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of PHI.

L. To the extent applicable, Business Associate must provide access to PHI in a Designated Record Set at reasonable times, at the request of Covered Entity or as directed by Covered Entity, to an Individual specified by Covered Entity in order to meet the requirements under 45 CFR § 164.524.

M. A Business Associate that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of health plan, must not use or disclose PHI that is genetic information for underwriting purposes, in accordance with the provisions of 45 CFR 164.502.

N. To the extent applicable, Business Associate must make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to, pursuant to 45 CFR § 164.526, at the request of Covered Entity or an Individual.

O. Business Associate must, upon request with reasonable notice, provide Covered Entity access to its premises for a review and demonstration of its internal practices and procedures for safeguarding PHI.

P. Business Associate must, upon request and with reasonable notice, furnish to Covered Entity security and privacy audit results, risk analyses, security and privacy policies and procedures, details of previous Breaches and Security Incidents, and documentation of controls.

Q. Business Associate must also maintain records indicating who has accessed PHI about an Individual in an electronic designated record set and information related to such access, in accordance with 45 C.F.R. § 164.528. Business Associate must document such disclosures of PHI and information related to such disclosures as would be required for a 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. Should an Individual make a request to Covered Entity for an accounting of disclosures of his or her PHI pursuant to 45 C.F.R. § 164.528, Business Associate must promptly provide Covered Entity with information in a format and manner sufficient to respond to the Individual's request.

R. Business Associate must, upon request and with reasonable notice, provide Covered Entity with an accounting of uses and disclosures of PHI that was provided to it by Covered Entity.

S. Business Associate must make its internal practices, books, records, and any other material requested by the Secretary relating to the use, disclosure, and safeguarding of PHI received from Covered Entity available to the Secretary for the purpose of determining compliance with HIPAA. Business Associate must make the aforementioned information available to the Secretary in the manner and place as designated by the Secretary or the Secretary's duly appointed delegate. Under this Agreement, Business Associate must comply and cooperate with any request for documents or other information from the Secretary directed to

Covered Entity that seeks documents or other information held or controlled by Business Associate.

T. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 42 C.F.R. § 164.502(j)(1).

U. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate or the Underlying Agreement, 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 be used or further disclosed only as Required By Law or for the limited purpose for which it was disclosed to the person, and the person must agree to notify Business Associate of any instance of any Breach, Security Incident, or use or disclosure of PHI not provided for by this Agreement of which it is aware in which the confidentiality of the information has been breached.

V. Business Associate understands that, pursuant to 45 CFR § 160.402, the Business Associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation of the HIPAA rules based on the act or omission of any agent of the Business Associate, including a workforce member or subcontractor, acting within the scope of the agency.

IV. TERM AND TERMINATION.

A. Term. The Term of this Agreement shall be effective as of the effective date of the Underlying Agreement, and shall terminate: (1) when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity; or, (2) if it is infeasible to return or destroy PHI, in accordance with the termination provisions in this Article IV.

B. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall:

1. 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 the time specified by Covered Entity, have the right to terminate this Agreement and to terminate the Underlying Agreement, and shall report the violation to the Secretary;

2. Have the right to immediately terminate this Agreement and the Underlying Agreement if Business Associate has breached a material term of this Agreement and cure is not possible, and shall report the violation to the Secretary; or

3. If neither termination nor cure is feasible, report the violation to the Secretary.

4. This Article IV, Term and Termination, Paragraph B, is in addition to the provisions set forth in Paragraph 27, Termination for Default of the General Conditions of Contract Between County and Contractor, attached to the Underlying Agreement, in which “Business Associate” is “Contractor” and “Covered Entity” is “County” for purposes of this Agreement.

C. Effect of Termination.

1. Except as provided in Section IV.C.2, upon termination or cancellation of this Agreement, for any reason, Business Associate must return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision applies to PHI that is in the possession of a subcontractor(s), employee(s), or agent(s) of Business Associate. Business Associate must not retain any copies of the PHI.

2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate must provide to Covered Entity written notification of the nature of the PHI and the conditions that make return or destruction infeasible. After written notification that return or destruction of PHI is infeasible, Business Associate must extend the protections of this Agreement to such PHI and limit further use(s) and disclosure(s) of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI. Notwithstanding the foregoing, to the extent that it is not feasible to return or destroy such PHI, the terms and provisions of this Agreement survive termination of this Agreement with regard to such PHI.

3. Should Business Associate violate this Agreement, HIPAA, the Underlying Agreement, the MCMRA, or other applicable law, Covered Entity has the right to immediately terminate any contract then in force between the Parties, including the Underlying Agreement.

V. CONSIDERATION. Business Associate recognizes that the promises it has made in this Agreement shall, henceforth, be reasonably, justifiably, and detrimentally relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

VI. CAUSES OF ACTION IN THE EVENT OF BREACH. As used in this paragraph, the term “breach” has the meaning normally ascribed to that term under the Maryland law related to contracts, as opposed to the specific definition under HIPAA related to PHI. Business Associate hereby recognizes that irreparable harm will result to Covered Entity in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in this Agreement, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of this Agreement. Furthermore, in the event of breach of this Agreement by Business Associate, Covered Entity is entitled to reimbursement and indemnification from Business Associate for Covered Entity's reasonable attorneys' fees and expenses and costs that were reasonably incurred as a proximate result of Business Associate's breach. The causes of action

contained in this Article VI are in addition to (and do not supersede) any action for damages and/or any other cause of action Covered Entity may have for breach of any part of this Agreement. Furthermore, these provisions are in addition to the provisions set forth in Paragraph 18, "Indemnification", of the General Conditions of Contract Between County and Contractor, attached to the Underlying Agreement in which "Business Associate" is "Contractor" and "Covered Entity" is "County", for purposes of this Agreement.

VII. MODIFICATION; AMENDMENT. This Agreement may be modified or amended only through a writing signed by the Parties and, thus, no oral modification or amendment hereof shall be permitted. 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 HIPAA, including its Privacy, Security, and Notice Rules.

VIII. INTERPRETATION OF THIS AGREEMENT IN RELATION TO OTHER AGREEMENTS BETWEEN THE PARTIES. Should there be any conflict between the language of this Agreement and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement, along with the Underlying Agreement, shall control and prevail unless the Parties specifically refer in a subsequent written agreement to this Agreement, by its title, date, and substance and specifically state that the provisions of the later written agreement shall control over this Agreement and Underlying Agreement. In any event, any agreement between the Parties, including this Agreement and Underlying Agreement, must be in full compliance with HIPAA, and any provision in an agreement that fails to comply with HIPAA will be deemed separable from the document, unenforceable, and of no effect.

IX. COMPLIANCE WITH STATE LAW. The Business Associate acknowledges that by accepting the PHI from Covered Entity, it becomes a holder of medical records information under the MCMRA and is subject to the provisions of that law. If HIPAA conflicts with another applicable law regarding the degree of protection provided for Protected Health Information, Business Associate must comply with the more restrictive protection requirement.

X. MISCELLANEOUS.

A. Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with HIPAA.

B. Regulatory References. A reference in this Agreement to a section in HIPAA means the section in effect, or as amended.

C. Notice to Covered Entity. Any notice required under this Agreement to be given Covered Entity shall be made in writing to:

Joy Page, Esq.
Deputy Privacy Official
Montgomery County, Maryland
401 Hungerford Drive, 7th Floor
Rockville, Maryland 20850

(240) 777-3247 (Voice)
(240) 777- 3099 (Fax)

Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Address: _____

Attention: _____

Phone: _____

D. Maryland Law. This Agreement is governed by, and shall be construed in accordance with, applicable federal law and the laws of the State of Maryland, without regard to choice of law principles.

E. Incorporation of Future Amendments. Other requirements applicable to Business Associates under HIPAA are incorporated by reference into this Agreement.

F. Penalties for HIPAA Violation. In addition to that stated in this Agreement, Business Associate may be subject to civil and criminal penalties noted under HIPAA, including the same HIPAA civil and criminal penalties applicable to a Covered Entity.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

MONTGOMERY COUNTY, MARYLAND

CONTRACTOR NAME

By: _____

Name: _____

Title: _____

Date: _____

By: _____

Name: James C. Bridgers, Jr., Ph.D., MBA

Title: Director, Department of Health
and Human Services

Date: _____

EXHIBIT A

FORM OF NOTIFICATION

This notification is made pursuant to Section III.F of the Business Associate Agreement between:

- Montgomery County, Maryland, (the “County”) and
- _____ (Business Associate).

Business Associate hereby notifies the County that there has been a Breach, Security Incident, or use or disclosure of PHI not provided for by the Business Associate Agreement (an “Incident”) that Business Associate has used or has had access to under the terms of the Business Associate Agreement.

Description of the Incident:

Date of the Incident: _____

Date of discovery of the Incident: _____

Does the Incident involve 500 or more individuals? Yes/No

If yes, do the people live in multiple states? Yes/No

Number of individuals affected by the Incident:

Names and addresses of individuals affected by the Incident:

(Attach additional pages as necessary) _____

The types of unsecured PHI that were involved in the Incident (such as full name, Social Security number, date of birth, home address, account number, or disability code):

Description of what Business Associate is doing to investigate the Incident, to mitigate losses, and to protect against any further Incidents:

Contact information to ask questions or learn additional information:

Name: _____

Title: _____

Address: _____

Email Address: _____

Phone Number: _____