

RIDER 111

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“Agreement”), effective _____, 201_ (“Effective Date”), is entered into by and between _____ with an address at _____ (the “Business Associate”) and The University of Texas MD Anderson Cancer Center, with an address at 1515 Holcombe Boulevard, Houston, Texas 77030 (the “Covered Entity”) (each a “Party” and collectively the “Parties”).

The Business Associate is **[identify the Bus. Assoc.’s legal status, such as an Indiana corporation, or a limited partnership, etc.]** and the Covered Entity is an institution of The University of Texas System and a State of Texas agency. The Parties have entered into one or more agreements (the “Services Agreement”) pursuant to which Business Associate is providing certain **[insert the kind(s) of services provided by the Bus. Assoc.]** (“Services”) to the Covered Entity that require the disclosure and use of Protected Health Information. Both Parties are committed to complying with the Privacy Rule and the Security Rule promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

This Agreement sets forth the terms and conditions pursuant to which Protected Health Information 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 each Services Agreement and after its termination. All capitalized terms in this Agreement that are used as defined terms herein have the meanings ascribed to them in Section 1 below, unless otherwise noted or the context clearly requires otherwise. The Parties agree as follows:

1. DEFINITIONS

1.1 **Administrative Safeguards.** “Administrative Safeguards” has the same meaning as the term “administrative safeguards” in 45 C.F.R. §164.304, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.2 **Breach.** “Breach” means the unauthorized acquisition, access, use, or disclosure of PHI that compromises the security or privacy of such information and poses a significant risk of financial, reputational, or other harm to the patient. A breach has not occurred, however, where the PHI is retrieved from the unauthorized person in such a manner that he or she would not reasonably have been able to retain such information.

1.3 **Designated Record Set.** “Designated Record Set” has the same meaning as the term “designated record set” in 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.4 **Electronic Protected Health Information.** “Electronic Protected Health Information” has the same meaning as the term “electronic protected health information” in 45 C.F.R. § 160.103, as such provision is currently drafted and as it is subsequently updated, amended or revised, but limited to the information created or received by Business Associate from or on behalf of Covered Entity.

1.5 Health Care Operations. “Health Care Operations” has the same meaning as the term “health care operations” in 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.6 Individual. “Individual” has the same meaning as the term “individual” in 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised, and will include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).

1.7 Physical Safeguards. “Physical Safeguards” has the same meaning as the term “physical safeguards” in 45 C.F.R. §164.304, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.8 Privacy Officer. “Privacy Officer” has the same meaning as the term “privacy officer” in 45 C.F.R. § 164.530(a)(1), as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.9 Privacy Rule. “Privacy Rule” means the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. part 160 and part 164, subparts A and E.

1.10 Protected Health Information. “Protected Health Information” has the same meaning as the term “protected health information” in 45 C.F.R. § 160.103, as such provision is currently drafted and as it is subsequently updated, amended or revised, but limited to the information created or received by Business Associate from or on behalf of Covered Entity.

1.11 Required by Law. “Required by Law” has the same meaning as the term “required by law” in 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.12 Secretary. “Secretary” means the Secretary of the Department of Health and Human Services or his designee.

1.13 Security Incident. "Security Incident" has the same meaning as the term “security incident” in 45 C.F.R. § 164.304, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.14 Security Rule. “Security Rule” means the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. parts 160, 162 and 164, subpart C.

1.15 Technical Safeguards. “Technical Safeguards” has the same meaning as the term “technical safeguards” in 45 C.F.R. §164.304, as such provision is currently drafted and as it is subsequently updated, amended or revised.

1.16 Unsecured PHI. "Unsecured PHI" means PHI that is not secured by a technology standard that (i) renders PHI unusable, unreadable, or indecipherable to unauthorized individuals, and (ii) is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

2. PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

2.1 Services. Pursuant to the Services Agreement, Business Associate provides Services for the Covered Entity that involve the use and disclosure of Protected Health Information. Except as otherwise specified herein, the Business Associate may make any and all uses of Protected Health Information necessary to perform its obligations under the Services Agreement. All other uses not authorized by this Agreement are prohibited. Moreover, Business Associate may disclose Protected Health Information for the purposes authorized by this Agreement only (i) to its employees, subcontractors and agents, in accordance with Sections 3.1(f) and 3.1(l); (ii) as directed by the Covered Entity; or (iii) as otherwise permitted by the terms of this Agreement including, but not limited to, Section 2.2(b) below.

2.2 Business Activities of the Business Associate. Unless otherwise limited herein, the Business Associate may:

- a. use the Protected Health Information in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of the Business Associate provided that such uses are permitted under state and federal confidentiality laws.
- b. disclose the Protected Health Information in its possession to third parties for the purpose of its proper management and administration or to fulfill any present or future legal responsibilities of the Business Associate, provided that the Business Associate represents to the Covered Entity, in writing, that (i) the disclosures are Required by Law; or (ii) the Business Associate has received from the third party written assurances regarding its confidential handling of such Protected Health Information as required under 45 C.F.R. § 164.504(e)(4).
- c. use and/or disclose Protected Health Information as permitted under 45 C.F.R. § 164.512 except that uses or disclosures for research are not permitted without prior approval by the Covered Entity.

2.3 Additional Activities of Business Associate. In addition to using the Protected Health Information to perform the Services set forth in Section 2.1 of this Agreement, Business Associate may:

- a. aggregate the Protected Health Information in its possession with the Protected Health Information of other covered entities that the Business Associate has in its possession through its capacity as a business associate to those other covered entities provided that the purpose of such aggregation is to provide the Covered Entity with data analyses relating to the Health Care Operations of the Covered Entity. Under no circumstances may the Business Associate disclose Protected Health Information of one covered entity to another covered entity absent the explicit authorization of the covered entity.
- b. de-identify any and all Protected Health Information provided that the de-identification conforms to the requirements of 45 C.F.R. § 164.514(b), and further

provided that the Covered Entity maintains the documentation required by 45 C.F.R. § 164.514(b) which may be in the form of a written assurance from the Business Associate. Pursuant to 45 C.F.R. § 164.502(d)(2), de-identified information does not constitute Protected Health Information and is not subject to the terms of this Agreement.

3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PROTECTED HEALTH INFORMATION

3.1 Responsibilities of the Business Associate. With regard to its use and/or disclosure of Protected Health Information, the Business Associate will:

- a. use and/or disclose the Protected Health Information only as permitted or required by this Agreement or as Required by Law and to use appropriate safeguards to prevent impermissible use or disclosure of PHI.
- b. report to the designated Privacy Officer of the Covered Entity, in writing, any use and/or disclosure of the Protected Health Information that is not permitted or required by this Agreement of which Business Associate becomes aware within two (2) business days of the Business Associate's discovery of such unauthorized use and/or disclosure.
- c. mitigate, to the greatest extent possible, any deleterious effects from any improper use and/or disclosure of Protected Health Information of which the Business Associate becomes aware and/or reports to the Covered Entity.
- d. implement Administrative, Physical and Technical Safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic Protected Health Information it creates, receives, maintains, or transmits on behalf of Covered Entity.
- e. use commercially reasonable efforts to maintain the security of the Protected Health Information and to prevent unauthorized use and/or disclosure of Protected Health Information.
- f. require all of its subcontractors and agents that receive or use, or have access to, Protected Health Information under this Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of Protected Health Information that apply to the Business Associate pursuant to Section 3 of this Agreement.
- g. ensure that any agent, including a subcontractor, agrees to implement reasonable and appropriate safeguards to 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.
- h. make available all records, books, agreements, policies and procedures relating to the use and/or disclosure of Protected Health Information to the Secretary, in the time and

manner designated by the Secretary, for purposes of the Secretary's determination that the Covered Entity has complied with the Privacy Rule, subject to attorney-client and other applicable legal privileges.

- i. within fourteen (14) days of receiving a written request from the Covered Entity, make available during normal business hours at Business Associate's offices all records, books, agreements, policies and procedures relating to the use and/or disclosure of Protected Health Information for purposes of enabling the Covered Entity to determine the Business Associate's compliance with the terms of this Agreement.
- j. within five (5) 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 Protected Health Information in accordance with 45 C.F.R. § 164.528.
- k. subject to Section 5.4 below, return to the Covered Entity or destroy, within one hundred eighty (180) days of the termination of this Agreement, the Protected Health Information in its possession and retain no copies (which for purposes of this Agreement means destroy all backup tapes).
- l. disclose to its subcontractors, agents or other third parties only the minimum Protected Health Information necessary to perform or fulfill a specific function required or permitted under the Services Agreement or this Agreement.
- m. report to the Director of Information Security of the Covered Entity, in writing, any Security Incident or unintentional use or disclosure of Unsecured PHI, identified internal/external breach of data, or disaster occurrence of which Business Associate becomes aware within two (2) business days of the Business Associate's discovery of such incident. The Business Associate must include the following information when reporting a breach:
 - (i) Identification of the individual whose Unsecured PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, used, or disclosed during a breach;
 - (ii) Circumstances of the breach;
 - (iii) Date of the breach;
 - (iv) Date of the discovery;
 - (v) Type of PHI involved (such as full name, Social Security number, date of birth, home address, account number, or medical record number); and
 - (vi) Any other additional information the Covered Entity requests.

This Section 3.1 will survive the termination of this Agreement solely with respect to the Protected Health Information that Business Associate retains in accordance with Section 5.4 below because it is not feasible to return or destroy such Protected Health Information.

3.2 Responsibilities of the Covered Entity. With regard to the use and/or disclosure of Protected Health Information by the Covered Entity to the Business Associate or the use and/or disclosure of Protected Health Information by the Business Associate, the Covered Entity will:

- a. provide Business Associate with a copy of its notice of privacy practices (the “Notice”) that the Covered Entity provides to Individuals pursuant to 45 C.F.R. §164.520.
- b. notify the Business Associate of any changes in, or revocation of, the consent or authorization provided to the Covered Entity by Individuals pursuant to 45 C.F.R. §164.506 or §164.508, to the extent such changes may affect Business Associate's use or disclosure of Protected Health Information.
- c. 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. parts 160 and 164 that may impact in any manner the use and/or disclosure of Protected Health Information by the Business Associate under this Agreement, including, but not limited to, restrictions on use and/or disclosure of Protected Health Information as provided for in 45 C.F.R. § 164.522 agreed to by the Covered Entity, to the extent such restrictions may affect Business Associate's use or disclosure of Protected Health Information.
- d. 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 the Covered Entity.

4. ADDITIONAL RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PROTECTED HEALTH INFORMATION

4.1 Responsibilities of the Business Associate with Respect to Handling of Designated Record Set. In the event that the Parties mutually agree in writing that the Protected Health Information constitutes a Designated Record Set, the Business Associate will:

- a. at the request of, and in the time and manner designated by the Covered Entity, provide access to the Protected Health Information to the Covered Entity or the Individual to whom such Protected Health Information relates or his or her authorized representative in order to meet a request by such Individual under 45 C.F.R. § 164.524.
- b. at the request of, and in the time and manner designated by the Covered Entity, make any amendment(s) to the Protected Health Information that the Covered Entity directs pursuant to 45 C.F.R. § 164.526. Provided, however, that the Covered Entity makes the determination that the amendment(s) are necessary because the Protected Health Information that is the subject of the amendment(s) has been, or could foreseeably be,

relied upon by the Business Associate or others to the detriment of the Individual who is the subject of the Protected Health Information to be amended.

4.2 Responsibilities of the Covered Entity with Respect to the Handling of the Designated Record Set. In the event that the Parties mutually agree in writing that the Protected Health Information constitutes a Designated Record Set, the Covered Entity will:

- a. notify the Business Associate, in writing, of any Protected Health Information that Covered Entity seeks to make available to an Individual pursuant to 45 C.F.R. § 164.524 and the time, manner and form in which the Business Associate will provide such access.
- b. notify the Business Associate, in writing, of any amendment(s) to the Protected Health Information in the possession of the Business Associate that the Business Associate will be required to make and inform the Business Associate of the time, form and manner in which such amendment(s) will be made.

4.3 Sections 4.1 and 4.2 of this Agreement will survive the termination of this Agreement, provided that Covered Entity determines that the Protected Health Information being retained pursuant to Section 5.4 below constitutes a Designated Record Set.

5. TERM AND TERMINATION

5.1 Term. This Agreement will become effective on the Effective Date and will 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 will survive its expiration or other termination in accordance with Section 5.4 herein. **[This provision may be omitted except in cases of a “stand alone” agreement.]**

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 Services Agreement 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 thirty (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. Nonetheless, in the event that mutually agreeable terms cannot be achieved within thirty (30) days, Business Associate must cure said breach to the satisfaction of the Covered Entity within thirty (30) days. Failure to cure in the manner set forth in this paragraph is grounds for the immediate termination of this Agreement and any Services Agreement. Nothing contained in this Section 5.2 will be deemed to require the Covered Entity to terminate this Agreement and the Services Agreement upon breach by Business Associate of a material term of this Agreement if termination is not feasible, and the Covered Entity will have the right to report any such breach to the Secretary as provided for under 45 C.F.R. § 164.504(e)(1)(ii).

5.3 Termination by Business Associate. If the Business Associate makes the determination that a material condition of performance has changed under any Services Agreement or this Agreement, or that the Covered Entity has breached a material term of this Agreement, Business

Associate may provide thirty (30) days written notice of its intention to terminate this Agreement and the Services 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 will not terminate this Agreement so long as any Services Agreement is in effect.

5.4 Effect of Termination. Upon termination of a Services Agreement, Business Associate will return or destroy all Protected Health Information pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(I), if it is feasible to do so. Prior to doing so, the Business Associate will recover any Protected Health Information in the possession of its subcontractors or agents. If it is not feasible for the Business Associate to return or destroy said Protected Health Information, the Business Associate will notify the Covered Entity in writing. The notification will include: (i) a statement that the Business Associate has determined that it is not feasible to return or destroy the Protected Health Information in its possession; and (ii) the specific reasons for such determination. Business Associate will extend any and all protections, limitations and restrictions contained in this Agreement to the Business Associate's use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information not feasible. If it is not feasible for the Business Associate to obtain, from a subcontractor or agent any Protected Health Information 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 Protected Health Information 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 Protected Health Information infeasible. Business Associate's obligations under this Section 5.4 will not apply to Protected Health Information that is the subject of other agreements between Covered Entity and Business Associate to the extent those other agreements survive the termination, and Business Associate may retain any Protected Health Information necessary to Business Associate's services under any other agreements with Covered Entity.

6. REPRESENTATIONS AND WARRANTIES [Note: This section will likely be omitted except when MDACC is completing a Business Associate Agreement as a "stand alone" contract, as opposed to an addendum or rider to an underlying service agreement.]

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

- a. 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. 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. 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. all of its employees, agents, representatives and members of its workforce, whose services may be used to fulfill obligations under this Agreement are or will 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 to which the Covered Entity has agreed to adhere regarding the use and disclosure of Protected Health Information of any Individual that materially affect and/or limit the uses and disclosures that are otherwise permitted under the Privacy Rule will be communicated to the Business Associate, in writing, and in a timely fashion.
- e. it will reasonably cooperate with the other Party in the performance of their mutual obligations under this Agreement and their respective obligations under HIPAA.

6.2 Representations and Warranties of Business Associate. Business Associate affirms, certifies, and warrants that it is not suspended, debarred, or listed in the U.S. General Services Administration's List of Parties Excluded From Federal Procurement or Non-Procurement Programs, or excluded from award by the United States Office of the Inspector General ("OIG") regarding Medicare, Medicaid, or other federal programs. Business Associate further acknowledges that Covered Entity is prohibited by federal regulations from allowing any employee, subcontractor or agent of Business Associate to work on site at Covered Entity's premises or facilities if that individual is not eligible to work on federal healthcare programs such as Medicare, Medicaid, or other similar federal programs. Therefore, Business Associate affirms, certifies, and warrants that it shall not assign any employee, subcontractor or agent that appears on the List of Excluded Individuals/Entities issued by the OIG to work on site at Covered Entity's premises or facilities. Business Associate affirms, certifies, and warrants that it shall perform an OIG sanctions check quarterly on each of its employees, subcontractors and agents during the time such employees, subcontractors and agents are assigned to work on site at Covered Entity's premises or facilities.

6.3 Each Party will immediately notify the other Party as soon as the Party becomes aware that any of the foregoing representations and warranties may be inaccurate or may become incorrect.

7. INDEMNIFICATION

The Parties will 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 Rule or the Security Rule, by the indemnifying party or its employees, directors, officers, subcontractors, agents or other members of its workforce. This indemnification provision is enforceable against Covered Entity only to the extent authorized under the constitution and laws of the State of Texas.

8. MISCELLANEOUS [Some of the provisions below may be omitted except in the case of a stand-alone agreement.]

8.1 Business Associate. For purposes of this Agreement, Business Associate will include the named Business Associate herein. However, in the event that the Business Associate is otherwise a covered entity under the Privacy Rule, 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.

8.2 Amendments; Waiver. This Agreement may not be modified, nor will any provision hereof be waived or amended, except in a writing duly signed by authorized representatives of the Parties. 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, the Security Rule and HIPAA. A waiver with respect to one event will not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

8.3 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor will 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.

8.4 Notices. Any notices to be given under this Agreement will 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:

Attn:
Fax No.

If to Covered Entity, to:

The University of Texas
MD Anderson Cancer Center
1515 Holcombe Boulevard
Houston, Texas 77030
Attn: Privacy Officer
Fax No. 713-745-6029

Each Party may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided.

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

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

8.7 Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule and the Security Rule.

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

Name: _____
Title: _____
Date: _____

Name: _____
Title: _____
Date: _____