**Business Associate Agreement: HIPAA Regulations**

This Business Associate Agreement ("Agreement"), effective ("Effective Date"), is entered into by and between Trialomics, Inc. (the "Business Associate") and Covered Entity ( the "Covered Entity"). Citations to the code of the Federal Regulations shall be read to include and require all subsequent, updated, amended or revised provisions.

**Definitions**

(a) Business Associate.  “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Trialomics, Inc. The Business Associate is performing services pursuant to the Agreement and for all purposes hereunder, Business Associate’s status shall be that of an independent contractor.

(b) Covered Entity.  “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Covered Entity].

(c) HIPAA Rules.  “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

(d) The following terms have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

**Obligations and Activities of Business Associate**

Business Associate agrees to:

(a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;

(b) Use appropriate safeguards to prevent use or disclosure of protected health information other than as provided for by the Agreement;

(c) Report to Covered Entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information and any security incident;

Business Associate will notify Covered Entity of breach within 30 days.

Covered Entity will notify Business Associate of any security risk, breach potential, or breach that the Covered Entity is made aware of.

(d) All subcontractors who create, receive, maintain, or transmit electronic protected health information on a Business Associate’s behalf maintain Business Associate Agreements equal or greater than the Business Associate Agreement with the original Covered Entity.

(e) Make available protected health information in a designated record set to the Covered Entity as necessary.

(f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity’s obligations under 45 CFR 164.526;

(g) Maintain and make available the information required to provide an accounting of disclosures to the Covered Entity as necessary to satisfy covered entity’s obligations under 45 CFR 164.528;

(h)  To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, to comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and

(i) The Business Associate as well as the Covered Entity will make each of their own HIPAA policies and procedures available to each other for purposes of determining compliance with the HIPAA Rules as needed.

**Permitted Uses and Disclosures by Business Associate**

1. Business Associate may only use or disclose protected health information in way specified in their job description.

(b) Business Associate may use or disclose protected health information as required by law.

(c) Business Associate agrees to make uses and disclosures and requests for protected health information consistent with the Covered Entity’s minimum necessary policies and procedures.

(d) Business Associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by the Covered Entity. If the Agreement permits the Business Associate to use or disclose protected health information for its own management and administration and legal responsibilities or for data aggregation services as set forth in optional provisions.

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.

Business Associate may disclose protected health information for the proper management and administration of Business Associate or to carry out the legal responsibilities of the Business Associate, provided the disclosures are required by law, or 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 purposes 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.

Business Associate may provide data aggregation services relating to the health care operations of the covered entity.

**Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

Covered Entity shall notify Business Associate of any limitation(s) in the notice of these privacy practices, to the extent that such limitation may affect Business Associate’s use or disclosure of protected health information.

Covered Entity shall notify Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect Business Associate’s use or disclosure of protected health information.

Covered Entity shall notify Business Associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect Business Associate’s use or disclosure of protected health information.

**Permissible Requests by Covered Entity**

Covered Entity shall not request Business Associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity.

**Term and Termination**

(a) Term. The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date Covered Entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement.

(c) Obligations of Business Associate Upon Termination (for any reason): Business Associate shall retain no copies of the protected health information.

( ) Upon termination of this Agreement for any reason, Business Associate shall return to Covered Entity 1) all protected health information received from Covered Entity, or 2) data created, maintained, or received by Business Associate on behalf of the Covered Entity, that the Business Associate still maintains in any form.

( ) Business Associate shall destroy all protected health information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form.

( ) Business Associate will obtain or ensure the destruction of protected health information created, received, or maintained by subcontractors.

( ) Business Associate shall:

* 1. Retain only that protected health information which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;
  2. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as business associate retains the protected health information;
  3. Not use or disclose the protected health information retained by Business Associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at which applied prior to termination; and

( ) Business Associate may transmit the protected health information to another Business Associate of the Covered Entity at termination, which will act as immediate and final termination of this Business Associate Agreement.

**Complaints**

The process for individuals to make complaints is as follows: The Covered Entity is required to receive, process, and document all complaints made by the Business Associate. The Business Associate will send any concerns or complaints via email to the Covered Entity.

**Miscellaneous**

The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

**Notices**

| If to Covered Entity, send notice to: | If to Business Associate, to: |
| --- | --- |
| [Insert Name of Covered Entity] | [Insert Name of Business Associate] |
| Attn: Privacy Officer | Attn: Privacy Officer |
|  | |
| [Insert Address] | [Insert Address] |
|  |  |
|  |  |

**No Third Party Beneficiaries**

Business Associate and Covered Entity do not intend, nor does anything expressed or implied in this Agreement intend to confer, upon any person other than Business Associate and Covered Entity, and their respective successor or assigns, any rights, remedies, obligations or liabilities whatsoever.

**APPROVED AND ACCEPTED BY:**



Business Associate Date

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



Covered Entity Date

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