

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“Agreement”) is entered into by and between Customer (“Covered Entity”) on behalf of itself including its affiliates and/or controlled healthcare organizations and Cepheid, a California corporation (“Business Associate”). Covered Entity and Business Associate are collectively referred to herein as the “Parties.”

WHEREAS, the Parties have entered into, or are entering into, or may subsequently enter into, one or more agreements whereby Business Associate performs certain functions, activities, or services (collectively “Underlying Agreements”) for or on behalf of Covered Entity that may involve the use or disclosure of Protected Health Information (as defined herein) and Electronic Protected Health Information (as defined herein); and

WHEREAS, this Agreement is intended to comply with the requirement for written assurances between the Parties as contemplated by the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E, as may be amended from time to time (the “Privacy Rule”) and the Security Standards for Health Insurance Reform at 45 C.F.R. Parts 160, 162 and 164, as may be amended from time to time (the “Security Rule”); and

WHEREAS, the “Health Information Technology for Economic and Clinical Health” (“HITECH”) Act, contained within the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5, 123 Stat. 226), modifies the Privacy Rule and the Security Rule (hereinafter, all references to the Privacy Rule and the Security Rule shall include all amendments to such rules as may be published from time to time in connection with HITECH, and all references to HITECH shall include any accompanying regulations whether in effect as of the effective date of this Agreement or subsequently promulgated); and

NOW, THEREFORE, in consideration of the Parties’ continuing obligations under the Underlying Agreements and the agreements herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and only if and to the extent the Underlying Agreements involve the use or disclosure of Protected Health Information (as defined herein) and Electronic Protected Health Information (as defined herein), the Parties agree as follows:

1. **Definitions**

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the Privacy Rule or the Security Rule.

- A. “Business Associate” has the meaning set forth above.
- B. “Breach” has the meaning given to such term in 45 C.F.R. § 164.402.
- C. “Covered Entity” has the meaning set forth above.

- D. “Data Use Agreement” has the meaning has the same meaning as the term “data use agreement” in 45 C.F.R. § 164.514(e)(4) of the Privacy Rule. Section 4 of this Agreement constitutes a Data Use Agreement.
- E. “Designated Record Set” has the same meaning as the term “designated record set” in 45 C.F.R. § 164.501 of the Privacy Rule.
- F. “Electronic Protected Health Information” (“ePHI”) has the same meaning as the term “electronic protected health information” in 45 C.F.R. § 160.103 of the Security Rule, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- G. “HITECH” Act has the meaning set forth above.
- H. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), as amended, together with its implementing regulations.
- I. “Individual” has the same meaning as the term “individual” in 45 C.F.R. § 160.103 of the Privacy Rule.
- J. “Limited Data Set” has the same meaning as the term “limited data set” as defined at 45 C.F.R. § 164.514(e)(1).
- K. “Privacy Rule” has the meaning set forth above.
- L. “Protected Health Information (“PHI”)” has the same meaning as the term “protected health information” in 45 C.F.R. § 160.103 of the Privacy Rule (including, without limitation, Electronic Protected Health Information), limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- M. “Required by Law” has the same meaning as the term “required by law” in 45 C.F.R. § 164.103 of the Privacy Rule.
- N. “Secretary” means the Secretary of the Department of Health and Human Services or his or her designee.
- O. “Security Incident” has the same meaning as the term “security incident” in 45 C.F.R. § 164.304 of the Security Rule.
- P. “Security Rule” has the meaning set forth above.
- Q. “Unsecured PHI” has the meaning given to such phrase in the Breach Notification Rule at 45 C.F.R. § 164.402.

2. **Obligations and Activities of Business Associate**

- A. Business Associate acknowledges and agrees that all PHI that is created or received by Covered Entity and used by or disclosed to Business Associate or created or received by Business Associate on Covered Entity's behalf shall be subject to this Agreement.
- B. Business Associate agrees to not use or disclose PHI other than as permitted or required by this Agreement or as Required by Law.
- C. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.
- D. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement, the Privacy Rule or the Security Rule.
- E. Business Associate agrees to notify Covered Entity promptly following discovery of any Breach of Unsecured PHI. Any notice pursuant to this Section 2(E) will include, to the extent possible, the identification of each Individual whose Unsecured PHI has been, or is reasonably believed by Business Associate, to have been accessed, acquired or disclosed during such Breach. Business Associate will also provide Covered Entity other available information that Covered Entity is required to include in its notification to the Individual.
- F. Business Associate agrees to report to Covered Entity any use or disclosure of PHI not provided for by this Agreement or any Security Incident of which it becomes aware.
- G. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate for, or on behalf of, Covered Entity agrees in writing to substantially similar restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- H. Within fifteen (15) days of receiving a written request from Covered Entity, Business Associate agrees to provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an Individual to inspect and obtain a copy of PHI about the Individual that is maintained in a Designated Record Set, for as long as the PHI is maintained in the Designated Record Set, in accordance with 45 C.F.R. § 164.524; to amend PHI or a record about the Individual in a Designated Record Set, for as long as PHI is maintained in the Designated Record Set, in accordance with 45 C.F.R. § 164.526; and for an accounting of the disclosures of the Individual's PHI in accordance with 45 C.F.R. § 164.528.

I. Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

3. **Permitted Uses and Disclosures by Business Associate**

A. Except as otherwise limited by this Agreement, Business Associate may use or disclose PHI to perform functions, activities or services for or on behalf of Covered Entity as contemplated by the Underlying Agreements provided that such use or disclosure does not violate the Privacy Rule or HITECH if done by Covered Entity.

B. Except as otherwise limited by this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the present and/or future legal responsibilities of the Business Associate.

C. Except as otherwise limited by this Agreement, Business Associate may disclose PHI (i) to carry out the present/or future legal responsibilities of the Business Associate or otherwise permitted or required by applicable law, and (ii) when Business Associate is acquired or merged with a third party, in which case, Business Associate reserves the right to transfer the PHI to a successor in interest that assumes Business Associate's obligations under this Agreement.

D. Except as otherwise limited by this Agreement, Business Associate may disclose PHI 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 PHI is disclosed that it will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any breaches in the confidentiality of the PHI.

E. Business Associate may use PHI to report violations of law to appropriate federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1).

F. Except as otherwise limited by this Agreement, Business Associate may use PHI to aggregate data as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B), including, without limitation, to create graphic or visual representations of such aggregate data, and use and disclose such aggregated data to others.

G. Except as otherwise limited by this Agreement, Business Associate may use PHI to create de-identified information sets provided that the de-identification

conforms to the requirements of 45 C.F.R. §164.514(b). Once de-identified, data is no longer subject to this Agreement.

H. Except as otherwise limited by this Agreement, Business Associate may use PHI to create a Limited Data Set, and may, pursuant to a Data Use Agreement as set forth in Section 4.1 between the Parties, use such Limited Data Set for its own research purposes or public health activities.

I. For **Cepheid C360 users only** that use the Cepheid C360 software under a related Underlying Agreement, except as otherwise limited by this Agreement, Business Associate may use PHI to create a Limited Data Set, and may, pursuant to a Data Use Agreement as set forth in Section 4 between the Parties, use Limited Data Set for its own research purposes and/or to disclose such Limited Data Set: (i) to other users of Business Associate's Cepheid C360 software, including in the form of graphic or visual representations of such Limited Data Set, for their research, public health activities related, or health care operations, or (ii) solely for the duration of the COVID-19 or other national public health emergency, to the White House Task Force for COVID-19, the Centers for Disease Control and Prevention, and other state and federal government agencies for public health activities related to the COVID-19 pandemic, or any other pandemic when Department of Health & Human Services and/or Office of Civil Rights allow Business Associate to make such disclosure.

4. **Data Use Agreement**

4.1 Pursuant to Section 3(H) hereof, Business Associate may receive from Covered Entity or create Limited Data Sets for Business Associate. With respect to any such Limited Data Set, Business Associate agrees that it will:

A. Use or disclose such Limited Data Set only for research, public health activities, or as required by law.

B. Use reasonable and appropriate physical, technical and administrative safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Section 4.1.

C. Report to Covered Entity any use or disclosure of a Limited Data Set not provided for in this Section 4.1 of which Business Associate becomes aware.

D. Ensure that any agent, including any subcontractor, to whom Business Associate provides the Limited Data Set agrees in writing to the same restrictions and conditions that apply to Business Associate under this Section 4.1 with respect to the Limited Data Set.

E. Not attempt to identify or contact any of the individuals whose PHI is included in the Limited Data Set.

4.2. Pursuant to Section 3(I) hereof, Covered Entity may receive Limited Data Sets from Business Associate. With respect to any such Limited Data Set, Covered Entity agrees that it will:

- A. Use or disclose such Limited Data Set only for research, public health activities, health care operations, or as required by law.
- B. Use reasonable and appropriate physical, technical and administrative safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Section 4.2.
- C. Report to Business Associate any use or disclosure of a Limited Data Set not provided for in this Section 4.2 of which Covered Entity becomes aware.
- D. Ensure that any agent, including any subcontractor, to whom Covered Entity provides the Limited Data Set agrees in writing to the same restrictions and conditions that apply to Covered Entity under this Section 4.2 with respect to the Limited Data Set.
- E. Not attempt to identify or contact any of the individuals whose PHI is included in the Limited Data Set.

5. **Obligations of Covered Entity on Behalf of Business Associate**

- A. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices in accordance with 45 C.F.R. § 164.520, to the extent that such limitation(s) may affect Business Associate's use or disclosure of PHI.
- B. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.
- C. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that it has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

6. **Security Rule and HITECH Responsibilities of the Business Associate**

With regard to its use and/or disclosure of ePHI, Business Associate hereby agrees to do the following:

- A. Comply with 45 C.F.R. §§ 164.308, 164.310, 164.312 and 164.316, with respect to ePHI, to prevent use or disclosure of ePHI other than as provided for by this Agreement.

B. Require all of its subcontractors and agents that create, receive, maintain, or transmit ePHI on behalf of the Business Associate to agree, in writing, to adhere to substantially similar restrictions and conditions (in all material respects) concerning ePHI that apply to Business Associate pursuant to Section 5 of this Agreement.

C. Report to Covered Entity any Security Incident of which it becomes aware that involves the Confidentiality, Integrity or Availability of the ePHI that it creates, receives, maintains or transmits for or on behalf of Covered Entity. The parties agree that this Section 6 satisfies any reporting required by Business Associate of attempted but Unsuccessful Security Incidents (as defined below) for which the parties agree no additional report shall be required. For purposes of this Agreement, “Unsuccessful Security Incidents” include but are not limited to activity such as “pings” and other broadcast attacks on Business Associate’s firewall, port scans, unsuccessful log-on attempts, denials of service and any other attempts to penetrate such computer networks or systems that do not result in unauthorized access, use or disclosure of ePHI.

D. Authorize termination of this Agreement by Covered Entity if Covered Entity determines that Business Associate has violated a material term of this Agreement, in accordance with this Section 6.

7. **Term and Termination**

A. Term. The Term of this Agreement shall be effective as of the date set forth in the Underlying Agreements, and shall terminate when all the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate for or on behalf of Covered Entity, is destroyed or returned to Covered Entity or, if it is infeasible to return or destroy the PHI, protections are extended to such information, in accordance with the termination provisions in this Section 7.

B. Termination for Cause. Upon Covered Entity’s or Business Associate’s knowledge of a material breach or violation by Business Associate of any provision of this Agreement, Covered Entity shall either:

(i) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate the Underlying Agreements if Business Associate does not cure the breach or end the violation within a reasonable time as specified by Covered Entity;

(ii) Immediately terminate the Underlying Agreements if Business Associate has breached or violated a material term of this Agreement and cure is not possible; or

(iii) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

C. Effect of Termination.

(i) Except as provided in paragraph (ii) of this Section 7, upon termination of the Underlying Agreements, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate for or on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI. This Agreement shall terminate when all such PHI is either destroyed or returned to Covered Entity.

(ii) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

8. **Notification**

With respect to notice pursuant to Section 2(E) above, notice to the Covered Entity shall be made by telephone or email (if number or email address provided) and followed promptly by a written notice to the contact listed in the Underlying Agreements. Any other notice to the Covered Entity required or provided for under this Agreement shall be made in writing and shall be either personally delivered, mailed by first class mail or sent via facsimile to the appropriate individual as listed in the Underlying Agreements. Either Party may designate a different address in writing to the other.

For notice to the Business Associate:

Cepheid

Attn: Legal/Privacy Department – BAA

904 Caribbean Drive

Sunnyvale, CA 94089

Fax: 408-400-8305, Telephone: 408-548-9190

with a copy to: privacy.officer@cepheid.com

For notice to the Covered Entity:

To the address listed in the Underlying Agreements

9. **Regulatory References**

A reference in this Agreement to a section in the Privacy Rule, the Security Rule or HITECH means the section as in effect or as amended.

10. **Amendment**

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 HITECH, as amended.

11. **Survival**

The respective rights and obligations of the Business Associate under Section 7 of this Agreement shall survive the termination of this Agreement.

12. **Interpretation**

Any ambiguity in this Agreement shall be resolved to permit compliance with the Privacy Rule, the Security Rule and HITECH, as amended. Any conflict between the terms of this Agreement and any other agreement relating to the same subject matter, which is a requirement of the Business Associate under HIPPA, the Privacy Rule, the Security Rule and HITECH, as amended, shall be resolved so that the terms of this Agreement supersede and replace the relevant terms of any such other agreement.

13. **Anti-Assignment**

Neither Party may assign either this Agreement or any of its rights, interests or obligations hereunder without the prior written approval of the other Party.

14. **Severability**

The provisions of this Agreement shall be severable, and if any provision of this Agreement shall be held or declared to be illegal, invalid or unenforceable, the remainder of this Agreement shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

15. **Governing Law**

Except to the extent that the Privacy Rule, the Security Rule, or HITECH, as amended, or other federal law applies, this Agreement and the obligations of the Parties hereunder will be governed by and interpreted in accordance with the laws of the State of California. The Parties agree that each is aware of and is deemed to have been notified of any applicable state or local laws, rules or regulations and each party agrees to comply with such applicable state laws, rules and regulations. The Parties agree that this Agreement is hereby deemed to be modified to comply with such applicable state or local laws, rules or regulations.