

HIPAA BUSINESS ASSOCIATE SUBCONTRACTOR AGREEMENT

This Business Associate Subcontractor Agreement (“Agreement”) is entered into by and between Cepheid (“Business Associate”) and Vendor (“Subcontractor”). Business Associate and Subcontractor collectively are referred to herein as the “Parties.”

WHEREAS, Business Associate provides services to customers that are Covered Entities under HIPAA (as defined below), involving the use, disclosure and/or creation of Protected Health Information (“PHI”);

WHEREAS, Business Associate is obligated under the respective business associate agreements and other agreements (collectively, “Business Associate Agreements”) entered into with Covered Entities to have all of its subcontractors and agents that receive, use or may have access to PHI to agree in writing to adhere to the same restrictions and conditions on the use and/or disclosure of PHI that apply to Business Associate pursuant to its Business Associate Agreement with the Covered Entity;

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

WHEREAS, Business Associate and Subcontractor desire to enter into this Agreement to address certain requirements that are applicable to Covered Entities and Business Associate (and, in certain instances, Subcontractor) pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (Pub. L. 104-191), as amended by, among other authorities, the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) (42 U.S.C. § 17921 et seq.) (a section of the American Recovery and Reinvestment Act of 2009), and various implementing regulations, including, as defined below, the Privacy Rule, Security Rule and Breach Notification Rule.

NOW, THEREFORE, in consideration of the Parties’ continuing obligations under the Underlying Agreements between the Parties, the agreements herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, 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) “Breach” has the meaning given to such term in 45 C.F.R. § 164.402.
- (B) “Breach Notification Rule” has the meaning given to such term in 45 CFR §§ 164.400-414.
- (C) “Covered Entity” shall have the same meaning as the term “covered entity” in 45 CFR § 160.103.
- (D) “Designated Record Set” has the same meaning as the term “designated record set” in 45 C.F.R. § 164.501 of the Privacy Rule.
- (E) “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.

- (F) “Individual” has the same meaning as the term “individual” in 45 C.F.R. § 160.103 of the Privacy Rule.
- (G) “Limited Data Set” has the same meaning as the term “limited data set” as defined at 45 C.F.R. § 164.514(e)(1).
- (H) “Privacy Rule” has the meaning given to such term in 45 C.F.R. Parts 160 and 164, Subparts A and E, as may be amended from time to time.
- (I) “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.
- (J) “Required by Law” has the same meaning as the term “required by law” in 45 C.F.R. § 164.103 of the Privacy Rule.
- (K) “Secretary” means the Secretary of the Department of Health and Human Services or his or her designee.
- (L) “Security Incident” has the same meaning as the term in 45 C.F.R. § 164.304 of the Security Rule.
- (M) “Security Rule” has the meaning given to such term in 45 C.F.R. Parts 160, 162 and 164, as may be amended from time to time .
- (N) “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 Subcontractor

- (A) Subcontractor acknowledges and agrees that all PHI that is created or received by Business Associate and used by or disclosed to Subcontractor or created or received by Subcontractor on Business Associate’s behalf shall be subject to this Agreement.
- (B) Subcontractor agrees to not use or disclose PHI other than as permitted or required by this Agreement or as Required by Law.
- (C) Subcontractor agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.
- (D) Subcontractor agrees to mitigate, to the extent practicable, any harmful effect that is known to Subcontractor of a use or disclosure of PHI by Subcontractor in violation of the requirements of this Agreement, the Privacy Rule or the Security Rule.
- (E) Subcontractor agrees to notify Business Associate promptly at privacy.officer@cepheid.com, in no event later than three (3) days, following discovery of any (i) Breach of Unsecured PHI, and/or (ii) any use or disclosure of PHI not provided for by this Agreement. 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 Subcontractor, to have been accessed, acquired or disclosed during such Breach. Subcontractor will also provide Business Associate

other available information that Subcontractor is required to include in its notification to the Individual or Covered Entity.

- (F) Subcontractor agrees to report to Business Associate any use or disclosure of PHI not provided for by this Agreement or any Security Incident of which it becomes aware.
- (G) Subcontractor agrees to ensure that any agent, including a subcontractor (if permitted to have subcontractors by Business Associate), to whom it provides PHI received from, or created or received by Subcontractor for, or on behalf of, Business Associate agrees in writing to substantially similar restrictions and conditions that apply through this Agreement to Subcontractor with respect to such information.
- (H) Within five (5) days of receiving a written request from Business Associate, provide to Business Associate such information as is requested by Business Associate to permit Business Associate to respond to a request by an Individual or Covered Entity 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) Subcontractor 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 Subcontractor on behalf of Business Associate, available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Business Associate's compliance with the Privacy Rule.

3. Permitted Uses and Disclosures by Subcontractor

- (A) Except as otherwise limited by this Agreement, the Subcontractor may use or disclose PHI to perform functions, activities or services for or on behalf of Business Associate as contemplated by the Underlying Agreements between the Parties; provided that such use or disclosure does not violate HIPAA, as defined above, if done by Covered Entity or Business Associate.
- (B) Except as otherwise limited by this Agreement, the Subcontractor may use PHI for the proper management and administration of Subcontractor or to carry out the present and/or future legal responsibilities of Subcontractor.
- (C) Except as otherwise limited by this Agreement, the Subcontractor may disclose PHI for the proper management and administration of Subcontractor, or that disclosures are Required by Law, provided that Subcontractor obtains reasonable assurances from the recipient 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 recipient, and the recipient notifies the Subcontractor of any breaches in the confidentiality of the PHI.
- (D) Subcontractor may use PHI to report violations of law to appropriate federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1).

4. Obligations of Business Associate

- (A) Business Associate shall notify the Subcontractor of any limitation(s) in the Covered Entity's notice of privacy practices in accordance with 45 C.F.R. § 164.520, to the extent that such limitation(s) may affect Subcontractor's use or disclosure of PHI.
- (B) Business Associate shall notify Subcontractor 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 Subcontractor's use or disclosure of PHI.

5. Security Rule and HITECH Act Responsibilities of the Subcontractor

With regard to its use and/or disclosure of ePHI, the Subcontractor 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 Subcontractor to agree, in writing, to adhere to substantially similar restrictions and conditions (in all material respects) concerning ePHI that apply to Subcontractor pursuant to Section 5 of this Agreement.
- (C) Promptly report to privacy.officer@cepheid.com, in no event later than three (3) days, following discovery of 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 Business Associate. The parties agree that this Section satisfies any reporting required by Subcontractor 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 Subcontractor'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 Business Associate if Business Associate determines that Subcontractor has violated a material term of this Agreement, in accordance with this Section 5.

6. 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 Business Associate to Subcontractor, or created or received by Subcontractor for or on behalf of Business Associate, is destroyed or returned to Business Associate or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section 6.
- (B) Termination for Cause. Upon Business Associate's or Subcontractor's knowledge of a material breach or violation by Subcontractor of any provision of this Agreement, Business Associate shall either:
 - (i) Provide an opportunity for Subcontractor to cure the breach or end the violation and terminate the Underlying Agreements and any other agreements between the Parties which involves the use or disclosure of PHI if Subcontractor does not cure the breach or end the violation within the time specified by Business Associate;

- (ii) Immediately terminate the Underlying Agreements and any other agreement between the Parties which involves the use or disclosure of PHI if Subcontractor has breached or violated a material term of this Agreement and cure is not possible; or
 - (iii) If neither termination nor cure is feasible, Business Associate shall report the violation to the Secretary.
- (C) Term of Underlying Agreements. Notwithstanding any other provisions regarding the termination of this Agreement, this Agreement shall remain in effect for so long as any agreement is in effect between Business Associate and Subcontractor for Subcontractor to perform activities or services for or on behalf of Business Associate. Upon the termination of any such agreement, this Agreement automatically terminates without notice.
- (D) Effect of Termination.
- (i) Except as provided in paragraph (ii) of this Section, upon termination of the Underlying Agreements, for any reason, Subcontractor shall return or destroy all PHI received from Business Associate, or created or received by Subcontractor for or on behalf of Business Associate. This provision shall apply to PHI that is in the possession of subcontractors or agents of Subcontractor. Subcontractor shall retain no copies of the PHI. This Agreement shall terminate when all such PHI is either destroyed or returned to Business Associate.
 - (ii) In the event that Subcontractor determines that returning or destroying the PHI is infeasible, Subcontractor 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 Subcontractor maintains such PHI.

7. Notification

All notices to the Business Associate required or provided for under this Agreement shall be made first via email to privacy.officer@cephheid.com, followed promptly in writing and shall be either personally delivered, mailed by first class mail or sent via facsimile to Cepheid, 904 Caribbean Drive, Sunnyvale, CA 94089, Attn: Legal/Privacy Dept - BAA, Fax: 408-400-8305, Telephone: 408-548-9190. Notices to Subcontractor will be made in writing and promptly sent to the contact listed in the Underlying Agreements. Either Party may designate a different address in writing to the other.

8. Amendment

The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Business Associate to comply with the requirements of HIPAA, as defined above.

9. Survival

The respective rights and obligations of Subcontractor under Section 6 of this Agreement shall survive termination of this Agreement.

10. Interpretation

Any ambiguity in this Agreement shall be resolved to permit compliance with HIPAA, as defined above. Any conflict between the terms of this Agreement and any other agreement relating to the same subject matter shall be resolved so that the terms of this Agreement supersede and replace the relevant terms of any such other agreement.

11. 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.

12. 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.

13. Governing Law

Except to the extent that HIPAA, as defined above, 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.