

## BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BAA”) forms part of the contract, including a commercial agreement, a service agreement or an order (the “Agreement”). This BAA is entered into by and between the Customer (as defined in the Agreement) and Leica (as defined in the Agreement,) and shall continue in full force and effect for the duration of the Agreement. Leica Biosystems (hereinafter referred to as the “Business Associate”) and Customer (hereinafter referred to as the “Covered Entity”) are hereinafter individually referred to as a “party” or collectively as the “parties”.

The Parties agree that where there is processing of Protected Health Information (as defined below) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and regulations promulgated by the U.S. Department of Health and Human Services (“HHS”) under the Agreement, the terms of this BAA will apply to that Agreement, whether or not expressly referenced in that Agreement.

### RECITALS

WHEREAS, Business Associate has been engaged to provide certain services to Covered Entity, and, in connection with those services, there may be instances where Covered Entity may need to disclose to Business Associate, or Business Associate may need to create on Covered Entity’s behalf, certain Protected Health Information (as defined below) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and regulations promulgated by the U.S. Department of Health and Human Services (“HHS”) to implement certain privacy and security provisions of HIPAA (the “HIPAA Regulations”), codified in 45 C.F.R. Parts 160 and 164; and

WHEREAS, pursuant to the HIPAA Regulations, all business associates of Covered Entity, as a condition of doing business with Covered Entity, must agree in writing to certain mandatory provisions regarding the privacy and security of Protected Health Information; and

WHEREAS, the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), enacted as part of the American Recovery and Reinvestment Act of 2009, imposed certain existing privacy and security obligations directly on business associates, as well

as added new privacy and security obligations with respect to both covered entities and business associates; and

WHEREAS, in those instances where Business Associate receives or creates Protected Health Information for or on behalf of Covered Entity, Business Associate and Covered Entity agree that the parties shall be bound by the terms of this Agreement.

NOW THEREFORE, IN CONSIDERATION OF THE FOREGOING, and the mutual promises and covenants contain herein, Business Associate and Covered Entity agree as follows:

## AGREEMENT

### 1. Definitions.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the HIPAA Regulations.

(a) “Designated Record Set” means a group of records maintained by or for Covered Entity that is (i) the medical records and billing records about individuals maintained by or for a covered health care provider, (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or (iii) used, in whole or in part, by or for Covered Entity to make decisions about individuals.

(b) “Electronic Protected Health Information” (“ePHI”) means individually identifiable health information that is transmitted by, or maintained in, electronic media.

(c) “Individual” has the same meaning as the term “individual” in 45 C.F.R. § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).

(d) “Protected Health Information” (“PHI”) has the same meaning as the term “protected health information” in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from, or on behalf of, Covered Entity. PHI includes ePHI.

(e) “Secretary” means the Secretary of the HHS or his/her designee.

(f) “Security Incident” means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

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

(a) *Specific Uses and Disclosures.* Business Associate shall not use or disclose PHI other than as permitted or required by this Agreement or as required by law.

(b) *Other Business Associates.* As part of its providing functions, activities, and/or services to Covered Entity, Business Associate may disclose information, including PHI, to other business associates of Covered Entity and may use and disclose information, including PHI, received from other business associates of Covered Entity as if this information was received from, or originated with, Covered Entity.

(c) *Safeguards for Protection of PHI.* Business Associate agrees to use appropriate safeguards to prevent the use or disclosure of PHI other than as provided for by this Agreement or as required by law, as required by 45 C.F.R. § 164.504(e)(2)(ii)(B). Business Associate agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI that it creates, receives, maintains, or transmits on behalf of Covered Entity, as required by the HITECH Act and 45 C.F.R. §§ 164.308, 164.310, 164.312 and 164.316.

(d) *Reporting of Unauthorized Uses or Disclosures and Security Incidents.* Business Associate agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement and any successful Security Incidents of which it becomes aware.

(e) *Notification of Breach.* In addition to the requirements of subsection 2(d) of this Agreement, Business Associate will report to Covered Entity, following discovery (as defined in the HITECH Act and 45 C.F.R. § 164.410) and without unreasonable delay any breach of unsecured PHI, as defined by the HITECH Act and 45 C.F.R. § 164.402. Such notice shall 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, as well as any other available information that Covered Entity is required to include in notification to the individual. Business Associate will promptly update its report to Covered Entity if further information becomes available thereafter. Business Associate will cooperate with Covered Entity in notifying affected individuals as required by law.

(f) *Subcontractors.* Business Associate agrees to ensure that any subcontractor that creates, receives, maintains, or transmits PHI on behalf of the Business Associate agrees in writing to the same restrictions, conditions and requirements that apply through this Agreement to Business Associate with respect to such PHI.

(g) *Authorized Access to PHI.* To the extent that Business Associate maintains PHI in a Designated Record Set and at the request of Covered Entity, Business Associate agrees to provide access to PHI in a Designated Record Set to Covered Entity or, as directed by Covered Entity, to an individual in order to meet the requirements under 45 C.F.R. § 164.524.

(h) *Amendment of PHI.* To the extent that Business Associate maintains PHI in a Designated Record Set, Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. § 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.526.

(i) *Secretary's Right to Audit.* Business Associate agrees to make its internal practices, books, and records 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 for purposes of the Secretary determining Covered Entity's or Business Associate's compliance with the HIPAA Regulations and the HITECH Act and its implementing regulations. No attorney-client or other legal privilege or the work product rule shall be deemed to have been waived by virtue of this obligation.

(j) *Accounting for Disclosures.* Business Associate agrees to document and maintain documentation of disclosures of PHI and to make available to Covered Entity information related to such disclosures as would be required for 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.

(k) *Data Aggregation Services.* Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to provide data aggregation services to Covered Entity.

(l) *Management and Administrative Functions of Business Associate.* Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate. Business Associate may disclose PHI for such purposes provided that (i) such disclosures are required by law, or (ii) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information 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 instances of which it is aware in which the confidentiality of the information has been breached.

(m) *Limit on Amount of PHI Used, Disclosed or Requested.* When using or disclosing PHI or when requesting PHI from or on behalf of Covered Entity, Business Associate shall limit such PHI, to the extent practicable, to the limited data set as defined by 45 C.F.R. § 164.514(e)(2) or, if needed, to the minimum necessary to accomplish the intended purpose of such use, disclosure or request in accordance with 45 C.F.R. § 164.502(b). Business Associate's use and disclosure of PHI shall be consistent with the Covered Entity's minimum necessary policies and procedures, a copy of which shall be provided to Business Associate by Covered Entity.

(n) *Prohibition of Sale of Electronic Health Records or PHI.* Business Associate shall not directly or indirectly receive remuneration in exchange for any PHI of an individual except as permitted by the HIPAA Regulations.

(o) *Performance of Covered Entity Obligations.* To the extent Business Associate is to carry out one or more Covered Entity obligations under 45 C.F.R. Part 164 Subpart E, Business Associate shall comply with the requirements of that Subpart that apply to the Covered Entity in the performance of such obligation.

(p) *Compliance With 45 C.F.R. Part 164 Subpart E.* Business Associate may not use or disclose PHI in a manner that would violate 45 C.F.R. Part 164 Subpart E if done by Covered Entity, except for the specific uses and disclosures set forth in Sections 2(k) and 2(l).

3. Obligations of Covered Entity.

(a) *Notice of Privacy Practices.* Covered Entity shall provide Business Associate with its Notice of Privacy Practices, as well as any changes to such notice.

(b) *Revocation of Permitted Use or Disclosure of PHI.* Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.

(c) *Minimum Necessary Policies and Procedures.* Covered Entity shall provide to Business Associate Covered Entity's minimum necessary policies and procedures.

(d) *Restrictions on Use of Disclosure of PHI.* Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522.

(e) *Requested Uses or Disclosures of PHI.* Except for data aggregation or management and administrative activities of Business Associate set forth in Sections 2(k) and 2(l), Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Regulations if done by Covered Entity.

4. Term and Termination.

(a) *Term.* Except as otherwise provided herein, this Agreement shall continue until 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.

(b) *Termination Without Cause.* Either party may terminate this Agreement without showing cause by the delivery of a written notice from the

terminating party to the other party. Such termination is effective thirty (30) days from the date that the party receives such notice.

(c) *Termination for Cause.*

(i) Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may inform Business Associate in writing of such breach and provide Business Associate an opportunity to cure the breach. If Business Associate does not cure the breach within a reasonable time, Covered Entity may terminate this Agreement upon written notice. Such termination is effective on the date that the Business Associate receives the termination notice from Covered Entity that states that Covered Entity wishes to terminate this Agreement under this provision and states the material term of this Agreement the Covered Entity believes has been violated by Business Associate.

(ii) Upon Business Associate's knowledge of a material breach by Covered Entity, Business Associate may inform Covered Entity in writing of such breach and provide Covered Entity an opportunity to cure the breach. If Covered Entity does not cure the breach within a reasonable time, Business Associate may terminate this Agreement upon written notice. Such termination is effective on the date that the Covered Entity receives the termination notice from Business Associate that states that Business Associate wishes to terminate this Agreement under this provision and states the material term of this Agreement the Business Associate believes has been violated by Covered Entity.

(d) *Effect of Termination.*

(i) Any termination and/or expiration of either this Agreement or any other agreements entered into by the parties will not affect the Covered Entity's obligation to pay for services rendered and expenses and charges incurred before termination or expiration, as well as additional services and charges incurred in connection with an orderly transition. Termination of this Agreement does not affect the continued effectiveness of any other agreement between the parties.

(ii) Except as provided in paragraph (iii) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity.

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

(iv) Upon termination of this Agreement for any reason, Business Associate, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall retain only that PHI which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities as set forth in Section 2(l).

5. Miscellaneous.

(a) *Amendment.* Business Associate and Covered Entity agree to take such action as is necessary to amend this Agreement from time to time to enable Covered Entity to comply with the requirements of the HIPAA Regulations. This Agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed and agreed to by Business Associate and Covered Entity.

(b) *Interpretation.* In the event of an inconsistency between the provisions of this Agreement and the mandatory terms of the HIPAA Regulations, as may be expressly amended from time to time by HHS or as a result of interpretations by HHS, a court, or another regulatory agency with authority over the parties, the interpretation of HHS, such court, or regulatory agency shall prevail. In the event of a conflict among the interpretations of these entities, the conflict shall be resolved in accordance with rules of precedence. Where provisions of this Agreement are different from those mandated by the HIPAA Regulations, but are nonetheless permitted by the Rule, the provisions of the Agreement shall control.

(c) *No Third Party Beneficiaries.* Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Business Associate and Covered Entity, and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

(d) *Notices.* Any notices to be given hereunder shall be made via U.S. Mail or express courier, or hand delivery to the respective address given below.

(e) *Regulatory References.* A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended, and for which compliance is required.

(f) *Subpoenas.* In the event that Business Associate receives a subpoena or similar notice or request from any judicial, administrative or other party arising out of or in connection with this Agreement, including, but not limited to, any unauthorized use or disclosure of PHI, Business Associate shall promptly forward a copy of such subpoena, notice or request to Covered Entity and afford Covered Entity the opportunity to exercise any rights it may have under law.

(g) *Survival.* The respective rights and obligations of Business Associate under Section 4(d) of this Agreement (Effect of Termination) shall survive the termination of this Agreement.

(h) *Governing Law.* This Agreement shall be governed by and construed in accordance with the laws of the State of Texas to the extent that the provisions of HIPAA, the HIPAA Regulations and the HITECH Act and its implementing regulations do not preempt the laws of the State of Texas.

(i) *Relationship of the Parties.* Covered Entity and Business Associate agree that Business Associate's services hereunder are being carried out as an independent contractor and not as an employee or agent of the Covered Entity.