



FORUM SOFTWARE LICENSE AND MAINTENANCE TERMS AND CONDITIONS

These *FORUM Software License and Maintenance Terms and Conditions* (“**Agreement**”) are applicable to any purchase order, quote, statement of work or other purchasing document or exhibit hereto (“**Schedule(s)**”) related to the FORUM clinical data management software including all Updates related thereto (“**Software**”), between Carl Zeiss Meditec, Inc. (“**Supplier**”) and the party(ies) listed on the applicable Schedule (“**Customer**”). Additionally, this Agreement is applicable to any Software-related maintenance and support services (“**Maintenance Services**”) and other services that may include implementation or professional services related to the Software (“**Professional Services**”), which will be quoted and billed separate from the purchase of Software or Maintenance Services.

1. License and Restrictions.

1.1. License Grant. During the Term of this Agreement, and provided that Customer complies with the restrictions set forth in subsection 1.2 (“**Restrictions**”) below, Supplier hereby grants to Customer a non-exclusive, non-transferable license (1) to use the Software in object code for Customer’s internal business purposes of storing, archiving, viewing Customer’s clinical data generated by ophthalmic instruments (“**Purpose**”), and (2) to make a reasonable number of copies for backup and archival purposes. Supplier authorizes any of Customer’s employees, consultants, and/or contractors to use the Software for the performance of their duties relating to the Purpose; provided that, such use shall be governed by Supplier’s procedures, including without limitation providing each user with a separate password and user name in order to utilize the Software. The Software is licensed to the Customer, and not sold.

1.2. Restrictions. Except as expressly authorized in this Agreement, (i) Customer will not copy or modify the Software, in whole or in part and (ii) Customer will not lease, lend or rent the Software, use the Software to provide service bureau, time sharing, rental, application services provider, software-as-a-service, hosting or other computer services to third-parties, or otherwise make the functionality of the Software available to third-parties. Customer acknowledges that the Software constitutes and contains certain intellectual property rights and trade secrets of Supplier and its licensors, and, in order to protect such trade secrets and other interests that Supplier and its licensors may have in the Software, Customer agrees not to disassemble, decompile or reverse engineer the Software nor permit any third-party to do so, except to the extent such restrictions are prohibited by law.

1.3. Relocation and Transferability of License. Customer may freely transfer the Software embedded in any Supplier provided equipment to backup locations on any Customer site. Customer shall have the right to use the Software on any such equipment at the new location, provided that, Customer provides prior written notice to Supplier of the new site and the date of the relocation.

2. Delivery and Acceptance. Supplier will deliver the Software to Customer in the manner and timeframe described on the Schedule. Unless otherwise specified in the Schedule, the Software will be deemed accepted upon the earlier of the following: (a) the Software is operating according to specifications and is ready for use; or (b) first clinical use of the Software. Shipping and handling charges, if applicable, will be invoiced with shipment, which shall be sent FCA ZEISS’ shipping points.

3. Professional Services. Upon request, Supplier may provide Customer with Professional Services for or related to the Software as may be described in one or more mutually agreed to Schedules, which shall contain items such as a description of the services, the services rate(s), and the services period. Customer shall reimburse Supplier for travel and per diem expenses incurred during on-site visits that are reasonable, necessary and pre-approved by Customer in writing for Supplier to perform its duties as specified in this Agreement. Supplier may enter into contractual arrangements with independent contractors or subcontractors (collectively referred to as “**Subcontractors**”) to perform or otherwise assist Supplier in providing the Professional Services or Maintenance Services, provided however, that Supplier will not be relieved of its obligations under this Agreement because of any act or failure to act by any such Subcontractor(s) and will be fully liable for all such acts and omissions of the Subcontractor(s).

4. Maintenance Services.

4.1. General Maintenance Services. Subject to the signing of a specific Schedule and payment of the applicable fees, Supplier will provide the Customer with certain Maintenance Services for the Software, including any corrections, fixes, modifications, and improvements to the Software made generally available to all of Supplier’s customers (“**Updates**”). Supplier and Customer will mutually agree upon the best method for implementing the Updates, e.g., whether Supplier will assist Customer in implementing the Updates or whether Supplier will provide the Updates to Customer for Customer’s implementation.

4.2. Exclusions to Maintenance Services. Supplier will have no obligation of any kind to provide Maintenance Services of any kind for problems in the operation or performance of the Software to the extent caused by any of the following (each, a “**Customer-Generated Error**”): (a) non-Supplier software or hardware products or use of the Software in conjunction therewith; (b) modifications to the Software made by any party without Supplier’s express written authorization; (c) Customer’s use of the Software other than as authorized in this Agreement or as provided in the documentation; or (d) Customer’s use of other than the most current version of the Software or any error corrections or updates thereto provided by Supplier. If Supplier determines that it is necessary to perform Maintenance Services for a problem in the operation or performance of the Software that is caused by a Customer-Generated Error, then Supplier will notify Customer thereof as soon as Supplier is aware of such Customer-Generated Error and Supplier will have the right to invoice Customer at Supplier’s then-current published time and materials rates for all such Maintenance Services performed by Supplier.

5. Intellectual Property. Customer expressly acknowledges that, as between Supplier and Customer, Supplier owns all worldwide right, title and interest in and to the Software, and any copies thereof, including all worldwide intellectual property rights therein. Customer will not delete or in any manner alter the copyright, trademark, and other proprietary rights notices appearing on the Software as delivered to Customer. Customer will reproduce such notices on all copies it makes of the Software. Supplier shall retain for Supplier all right, title and interest in any intellectual property created when performing any Professional Services, Maintenance Services or creating any other deliverables under this Agreement.

6. Payment and Terms.

6.1. Fees and Payment. Customer will pay Supplier the applicable fees for all Software, Professional Services and Maintenance Services specified in an accepted Schedule. The Schedule may include one-time and recurring fees. Recurring fees will be invoiced annually, quarterly or monthly, unless otherwise specified in the Schedule. All such fees and expenses will be due and payable within thirty (30) days after Customer’s receipt of Supplier’s invoice, unless otherwise specified in the Schedule. All past due amounts will incur interest at a rate of one and a half percent (1.5%) per month or the maximum rate permitted by law, whichever is less.

6.2. Payment Terms. Customer will pay all amounts due under this Agreement in U.S. currency, unless otherwise specified in the applicable Schedule. All fees payable under this Agreement are net amounts and are payable in full, without deduction for taxes or duties of any kind. Customer will

be responsible for, and will promptly pay, all taxes and duties of any kind (including but not limited to sales, use and withholding taxes) associated with this Agreement or Customer's receipt or use of the Software, Professional Services and Maintenance Services, except for taxes based on Supplier's income. For Supplier to extend tax-exemption status to Buyer, Buyer must provide a tax-exemption certificate valid in the jurisdiction of the installation location prior to acceptance of the order.

7. Warranties and Disclaimer.

7.1. Warranty. Supplier warrants: (a) the Professional Services and Maintenance Services will be performed in a professional and workmanlike manner; and (b) that for period of ninety (90) days after the acceptance date ("**Warranty Period**"), the Software will operate without a material deviation between the general release version of the Software and its documentation (as updated to the particular time in question through the Maintenance Services, not including any modifications as part of the Professional Services). Upon any failure of the Software to function in conformance with its documentation during the Warranty Period, Supplier shall promptly, and at no charge to Customer, repair or replace the Software.

7.2. DISCLAIMER OF WARRANTIES. EXCEPT AS PROVIDED HEREIN, SUPPLIER DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT, AND ANY WARRANTIES ARISING OUT OF COURSE OF DEALING, USAGE OR TRADE. NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED FROM SUPPLIER OR ELSEWHERE WILL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN THIS AGREEMENT.

8. Indemnification. Supplier will defend Customer and Customer's officers, directors, from any allegations, claims, actions, suits or loss arising out of or relating to any claims of infringement of a third-party's intellectual property rights arising from Customer's use or possession of the Software provided that Customer: (a) promptly notifies Supplier in writing of the claim, provided however that the failure to promptly notify Supplier shall not reduce or affect the obligations of Supplier with respect thereto, except to the extent that Supplier is prejudiced thereby; and (b) provides Supplier, at Supplier's expense, with all assistance, information and authority reasonably required for the defense and settlement of the claim. If Customer's use or possession of any part of the Software is or is likely to be enjoined as an infringement of any third-party intellectual property rights, Supplier shall, at Supplier's option: (i) procure for Customer the right to continue to use the Software under the terms of this Agreement; or (ii) replace or modify the Software so that it is non-infringing. Supplier shall not be required to indemnify and hold Customer harmless from any intellectual property right infringement claim that results from: (A) Software and/or services based on Customer's specifications; (B) modifications made to any of the Software and/or services without Supplier's prior written approval; (C) use of the Software and/or services by Customer other than in accordance with the provisions of this Agreement; (D) use of the Software and/or services by Customer with other hardware, software or any combination thereof other than in accordance with the provisions of this Agreement or other than as recommended by Supplier; or (E) infringement of any hardware or software not manufactured by Supplier or any of its affiliates. THE PROVISIONS OF THIS SECTION 8 SET FORTH SUPPLIER'S SOLE AND EXCLUSIVE OBLIGATIONS, AND CUSTOMER'S SOLE AND EXCLUSIVE REMEDIES, WITH RESPECT TO INFRINGEMENT OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY RIGHTS OF ANY KIND.

9. Limitation of Liability. NEITHER PARTY SHALL HAVE ANY LIABILITY IN REGARD TO CONSEQUENTIAL, EXEMPLARY, SPECIAL, INCIDENTAL OR PUNITIVE DAMAGES, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL EITHER PARTY'S TOTAL LIABILITY IN CONNECTION WITH OR UNDER THIS AGREEMENT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORY OF LAW) EXCEED THE FEES PAID BY CUSTOMER UNDER THIS AGREEMENT. The parties expressly acknowledge and agree that Supplier has set its prices and entered into this Agreement in reliance upon the limitations of liability specified herein, which allocate the risk between Customer and Supplier and form a basis of the bargain between the parties.

10. Confidential Information. Each party ("**Receiving Party**") acknowledges that, in the course of the performance of this Agreement, it may learn certain confidential and proprietary information about the other party's ("**Disclosing Party**") business and operations that has been identified as "confidential" or proprietary or that the Receiving Party knows or has reason to know to be confidential, including, without limitation, patient data, information or personal health information ("**Confidential Information**"). Receiving Party agrees that it will keep all such information strictly confidential, and that it will not use it for any other purpose other than to exercise its rights and responsibilities under this Agreement, that it will not resell, transfer, or otherwise disclose such information to any third-party without the Disclosing Party's specific, prior written consent. Receiving Party agrees that Disclosing Party is and shall remain the exclusive owner of Confidential Information disclosed hereunder and all patents, copyrights, trade secrets, trademarks and other intellectual property rights therein. Receiving Party shall, upon the request of Disclosing Party, return to Disclosing Party all drawings, documents and other tangible manifestations of Confidential Information received by Receiving Party pursuant to this Agreement (and all copies and reproductions thereof). The obligations in this provision shall remain in effect following termination of this Agreement. Specifically excluded from the parties' confidentiality obligation is all information that: (a) was in the Receiving Party's legitimate possession prior to receipt of such information from Disclosing Party; (b) that can be proven to have been independently developed by personnel of Receiving Party; (c) was rightfully received from third parties and, to the best knowledge of Receiving Party, without an obligation of confidentiality to Disclosing Party; (d) is in the public domain through means other than by breach of this Agreement by Receiving Party; or (e) is disclosed pursuant to any judicial or government request, requirement or order, provided that the Receiving Party takes reasonable steps to provide the Disclosing Party the ability to contest such request, requirement or order. The parties acknowledge that Confidential Information has competitive value and that irreparable damage may result to the Disclosing Party if the Receiving Party discloses Confidential Information. The parties agree that legal proceedings at law or in equity, including injunctive relief, are appropriate in the event of a breach hereof without the duty of posting bond.

11. Term and Termination.

11.1. Term and Termination. This Agreement shall become effective as of delivery of the Software to Customer and shall continue for the term specified on a Schedule ("**Initial Term**"), and shall automatically renew for successive one-year periods unless this Agreement is otherwise terminated pursuant to the terms in this Section. Either party may elect not to renew this Agreement for subsequent one-year terms upon written notice to the other Party ninety (90) days' prior to the end of the Initial Term or any such subsequent terms. If either party fails to comply with any of the material provisions of this Agreement, the non-breaching party may terminate this Agreement upon thirty (30) days' prior written notice to the breaching party unless within the notice period (or any extension of the notice period), the breach is cured.

11.2. Effect of Termination. Upon termination of this Agreement by either party, Supplier will cease to provide Maintenance Services and Professional Services to Customer. Any additional requested technical support will be billed separately on a time and materials basis.

12. Compliance.

12.1. Compliance with Laws. By entering into this Agreement, the parties specifically intend to comply with all applicable state and federal laws, rules and regulations, including (i) the personal services safe harbor of the federal anti-kickback statute (42 U.S.C. 1320a-7(b)) and in particular, that the services performed under the Agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395nn) and (iii) federal and state privacy laws.

12.2. Access to Records. In accordance with Section 952 of the Omnibus Reconciliation Act of 1980, which amended Section 1861(v)(1) of the Social Security Act, and the regulations promulgated thereunder, so that the costs of services furnished under this Agreement by Company can be included for Medicare reimbursement purposes, Supplier will make available to the Secretary of Health and Human Services and the Comptroller General of the United States shall, upon written request, have access to such books, documents and records of Supplier necessary to verify the nature and extent of the costs of the services provided by Supplier. Access will be granted during the term of this Agreement until the expiration of four (4) years after the services being

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provided hereunder are furnished. Access will also be granted to any books, documents or records related to this Agreement between Supplier and organizations related to Supplier; provided, however, that such access shall be limited to books, documents and records on an as needed basis.

12.3. HIPAA. Supplier acknowledges that Customer is a Covered Entity and Supplier may be a Business Associate, when performing certain activities, for purposes of the Health Insurance Portability and Accountability Act of 1996 and the related regulations, as they may be amended from time to time ("HIPAA"). Accordingly, when applicable, the parties agree to comply with the terms and conditions of the Business Associate Agreement ("BAA") attached as Exhibit A and incorporated by this reference. If Supplier and Customer have an active prior fully executed BAA in place, such prior BAA shall govern for the purpose of the Covered Entity's compliance with HIPAA.

12.4. Discount Disclosure. All rebates and other discounts provided under this Agreement are intended to comply with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). To the extent required by 42 C.F.R. § 1001.952(h) (the Anti-Kickback Statute safe harbor regulations) or other applicable laws or regulations, the Customer shall fully and accurately reflect in cost reports or other submissions to federal healthcare programs all discounts provided under this Agreement and, upon request by the Secretary of the U. S. Department of Health and Human Services or a state agency, shall make available information provided to the Buyer by ZEISS concerning the discounts.

12.5. Compliance Related Changes. The parties recognize that the law and regulations may change or may be clarified, and that terms of this Agreement may need to be revised, on advice of counsel, in order to remain in compliance with such changes or clarifications, and the parties agree to negotiate in good faith revisions to the term or terms that cause the potential or actual violation or noncompliance. In the event the parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, either party may terminate this Agreement on thirty (30) days written notice to the other party, or earlier if necessary to prevent noncompliance with a deadline or effective date.

13. General Terms.

13.1. Choice of Law; Jurisdiction. This Agreement shall be governed by New York law and controlling United States federal law, without regard to the choice or conflict of laws provisions of any jurisdiction, and any disputes, actions, claims or causes of action arising out of or in connection with this Agreement. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sales of Goods, the application of which is expressly excluded.

13.2. Export Control. Customer agrees to comply fully with all relevant and applicable export laws and regulations of the United States ("**Export Laws**") to ensure that neither the Software, nor any direct product thereof are: (a) exported or re-exported directly or indirectly in violation of Export Laws; or (b) used for any purposes prohibited by the Export Laws, including but not limited to nuclear, chemical, or biological weapons proliferation.

13.3. Relationship of the Parties. No joint venture, partnership, employment, or agency relationship exists between Customer and Supplier as a result of this Agreement or use of the Software or any related Professional Services or Maintenance Service.

13.4. Waiver. The failure of either party to enforce any right or provision in this Agreement shall not constitute a waiver of such right or provision unless acknowledged and agreed to by the party in writing.

13.5. Non-Solicitation. Neither party shall directly solicit for employment the other party's personnel involved with this Agreement for one (1) year from the last date Professional Services are performed except with approval in writing from an authorized officer of the solicited party. This section does not limit any employee from answering general job postings.

13.6. Severability. If for any reason a court of competent jurisdiction finds any provision of this Agreement invalid or unenforceable, that provision of the Agreement will be enforced to the maximum extent permissible and the other provisions of this Agreement will remain in full force and effect.

13.7. Assignment. Neither party shall have the right to assign this Agreement or any of the rights or obligations hereunder without the prior written consent of the other party. Notwithstanding the foregoing, ZEISS may freely assign this Agreement to an affiliate, subsidiary, or successor to that area of its business to which this Agreement is related that is controlled by, has control over, or is under common control with ZEISS. Subject to the limitations on assignment set forth in this paragraph, this Agreement will apply to, be binding in all respects upon, and inure to the benefit of, the successors and permitted assigns of the parties.

13.8. Survival. The following sections shall survive termination or expiration of this Agreement for any reason: 5 ("Intellectual Property"), 6 ("Payment and Terms"), 7.2 ("Disclaimer of Warranties"), 8 ("Indemnification"), 9 ("Limitation of Liability"), 10 ("Confidential Information"), 11.2 ("Effect of Termination"), 12.2 ("Access to Records"), and 13 ("General Terms").

13.9. Force Majeure. The obligations of either party to perform under this Agreement shall be excused during each period of delay caused by matters (not including lack of funds or other financial causes) such as strikes, utility interruptions, Supplier delays, shortages of raw materials, government orders, acts of God, fires, floods, natural disasters, epidemics, pandemics, quarantine restrictions, other catastrophes, wars, civil disturbances, terrorism, riots, or other circumstances that are reasonably beyond the control of the party obligated to perform. Each party shall use commercially reasonable efforts to recommence performance as soon as reasonably practicable.

13.10. Notices. All notices or other communications required or permitted to be given under this Agreement shall be in writing (unless otherwise specifically provided herein) and delivered to the address listed on the applicable Schedule or as otherwise specified by a party.

13.11. Conflicting Terms. Unless otherwise mutually agreed in writing, in the event that any terms and/or conditions in this Agreement conflict or are inconsistent with any terms and/or conditions in any attached and incorporated agreement, including but not limited to Customer's standard terms and conditions of sale, amendments, addenda, exhibits and statements of work, then the terms and conditions of this Agreement shall control.

13.12. Entire Agreement. This Agreement, together with any applicable Schedules, represents the entire agreement between Supplier and Customer with respect to the Software, Maintenance Services, and Professional Services, obligations, and responsibilities to be performed by the parties hereunder. Supplier and Customer agree that all other agreements, proposals, purchase orders, representations and other understandings concerning the subject matter of this Agreement, whether oral or written, expressed or implied, between the parties are superseded in their entirety by this Agreement. The parties further agree that there are no promises, conditions, undertakings, or warranties, whether oral or written, expressed or implied, between them, other than as set forth herein. No alterations or modifications of this Agreement will be valid unless made in writing and signed by the parties. No attachment, supplement or exhibit to this Agreement shall be valid unless initiated by an authorized signatory of Supplier and Customer.

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EXHIBIT A

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "**Agreement**") is entered into by and between Carl Zeiss Meditec, Inc. ("**ZEISS**" or "**Business Associate**") and the Customer (as defined in the FORUM Software License Terms and Conditions) ("**Covered Entity**").

1. **Scope.**

- A. This Agreement sets forth the terms and conditions that shall govern Covered Entity's disclosure of Protected Health Information to ZEISS and its subsidiaries and affiliates, to the extent ZEISS meets the definition of, and in its capacity as, a Business Associate (defined below), in connection with the provision of certain Services (defined below) to Covered Entity as set forth in any agreement as described under Paragraph 2.P of this Agreement. This Agreement is not intended to amend, modify, or otherwise alter the rights, duties, and obligations of the parties under any other agreements between them. This Agreement also is not intended to grant any rights to any person or entity who is not a signatory to this Agreement. This Agreement only applies to the extent ZEISS is a Business Associate to Covered Entity under the HIPAA Rules (defined below).
- B. This Agreement is intended for compliance with applicable requirements of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), as amended by the Health Information Technology for Economic and Clinical Health Act, Division A of Title XIII of the American Recovery and Reinvestment Act of 2009, Public Law 111-005 (the "**HITECH Act**").

2. **Definitions.** Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the HIPAA Rules:

- A. "Breach" has the meaning set forth in 45 C.F.R. § 164.402.
- B. "Breach Notification Rule" has the meaning set forth in 45 C.F.R. Parts 160 and 164, Subpart D.
- C. "Business Associate" has the meaning set forth in 45 C.F.R. § 160.103.
- D. "Covered Entity" shall generally have the same meaning as the term "covered entity" 45 C.F.R. § 160.103, and in reference to the party to this agreement, shall mean the entity named as the Covered Entity in the introductory paragraph above.
- E. "Designated Record Set" has the meaning set forth in 45 C.F.R. § 164.501.
- F. "Electronic Protected Health Information" or "ePHI" has the meaning set forth in 45 C.F.R. § 160.103.
- G. "HIPAA Rules" shall mean the Privacy, Security and Breach Notification Rules.
- H. "Individual" has the meaning set forth in 45 C.F.R. § 160.103.
- I. "Limited Data Set" has the meaning set forth in 45 C.F.R. § 164.514(e)(2).
- J. "Privacy Rule" has the meaning set forth in the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E.
- K. "Protected Health Information" or "PHI" has the meaning set forth in 45 C.F.R. § 160.103, provided, however that it is limited to PHI created, maintained or received by Business Associate from or on behalf of Covered Entity.
- L. "Required by Law" has the meaning set forth in 45 C.F.R. § 164.103.
- M. "Secretary" means the Secretary of the Department of Health and Human Services or his or her designee.
- N. "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.
- O. "Security Rule" has the meaning set forth in the Security Standards at 45 C.F.R. Parts 160, 162, and 164, Subparts A and C.
- P. "Services" means those services Business Associate provides to Covered Entity and documented by a written agreement between Covered Entity and Business Associate, under which Business Associate provides services involving access to or the exchange of PHI.
- Q. "Subcontractor" shall have the same meaning as the term "subcontractor" in 45 C.F.R. § 160.103. If not capitalized herein, "subcontractor" shall have its general meaning in this Agreement.

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

- A. **Legal Compliance: Appropriate Safeguards.** Business Associate agrees to (1) not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required By Law, and (2) use reasonable safeguards and comply with the Security Rule with respect to ePHI, to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- B. **Reporting of Unauthorized Use and Disclosures.** Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement, including Breaches of unsecured PHI and Security Incidents, of which it becomes aware, as described below.
- C. **Reporting of Breaches.** Business Associate agrees to notify Covered Entity without unreasonable delay and in no case later than sixty (60) calendar days after the discovery of any Breach of Unsecured Protected Health Information. A Breach shall be treated as discovered by Business Associate as of the first day on which the Breach (i) is known to an employee, officer, or other agent of Business Associate (except the person committing the Breach), or (ii) by exercising reasonable diligence, would have been known to an employee, officer, or other agent of Business Associate (except the person committing the Breach). The notice shall include, to the extent possible, the identification of each individual whose unsecured Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used or disclosed during the Breach, as well as any other available information set forth in 45 C.F.R. §164.410(c)(2). Business Associate shall supplement its notice as facts become available.
- D. **Reporting of Security Incidents.** Business Associate shall report any Security Incident promptly (but in no event later than fifteen (15) business days upon becoming aware of such incident. However, the parties acknowledge and agree that this section constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence of attempted but Unsuccessful Security Incidents (as defined below) for which no further notice to Covered Entity shall be required. "Unsuccessful Security Incidents" shall include, but not be limited to, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denials of service and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of PHI.
- E. **Limitations on Use for Marketing Purposes.** Business Associate is specifically prohibited from using or disclosing PHI in violation of the marketing prohibitions set forth in the HIPAA Rules. Business Associate shall not use or disclose PHI for fundraising. Except as permitted under 45 C.F.R. § 164.502(a)(5)(ii), Business Associate agrees that it shall not directly or indirectly receive remuneration in exchange for PHI from or on behalf of the recipient of such PHI.
- F. **Subcontractors.** Business Associate agrees, per 45 C.F.R. §§ 164.502(e)(1)(ii) (Privacy Rule) and 164.308(b)(2) (Security Rule) to ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of Business Associate agree to at least the same restrictions, conditions and requirements that apply to Business Associate with respect to such information.
- G. **Documentation of Disclosures.** If applicable, Business Associate agrees to document any disclosures of Protected Health Information and 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 Protected Health Information in accordance with 45 C.F.R. § 164.528 as amended, and, within fifteen (15) business days of receiving such request from Covered Entity, provide such information to Covered Entity. If an Individual submits a request for an accounting to Business Associate, Business Associate shall, within fifteen (15) business days of receipt, forward the request to Covered Entity.
- H. **Access to Records.** If applicable, within ten (10) business days of a request by Covered Entity, Business Associate shall make available to Covered Entity for inspection and duplicating any PHI in a Designated Record Set, so that Covered Entity may meet its access obligations under the Privacy Rule at 45 C.F.R. § 164.524. If an Individual submits a request for access to Business Associate, Business Associate shall, within ten (10) business days of receipt, forward the request to Covered Entity.
- I. **Amendment of Records.** If applicable, Business Associate shall inform Covered Entity within ten (10) business days of receipt of any request by or on behalf of an Individual who is the subject of the PHI to amend the PHI that Business Associate maintains for or on behalf of Covered Entity in a Designated Record Set. If applicable, Business Associate shall, within twenty (20) business days of receipt of a written request, make the subject's PHI available to Covered Entity as may be required to fulfill Covered Entity's obligations to amend PHI pursuant to the HIPAA Rules, including, but not limited to, 45 C.F.R. § 164.526. Business Associate shall incorporate any amendments to Covered Entity's PHI into copies of such PHI maintained by Business Associate.
- J. **Designated Record Set.** Covered Entity and Business Associate agree that PHI received by Business Associate in connection with providing the Services described herein is not intended to, and as a general matter does not, qualify as a Designated Record Set.
- K. **Compliance with 45 C.F.R. part 164 Subpart E.** In the event Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. part 164 (Privacy of IIHI), Business Associate will comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).
- L. **Availability of Books and Records.** Business Associate will make its internal practices, books and records relating to its use and disclosure of Protected Health Information it creates, receives, transmits or maintains for or from Covered Entity available to the Secretary to determine compliance with the HIPAA Rules.

4. **Permitted Uses and Disclosures; Minimum Standard of Privacy Rule.**

- A. **Permitted Uses and Disclosures by Business Associate.** Business Associate may only use and disclose PHI as necessary to perform Services set forth in any agreement, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity, except for the specific uses and disclosures set forth in Subsections (1) through (4) below:
- (1) **Use and Disclosures Permitted by Law.** Business Associate may use and disclose PHI as Required by Law.
 - (2) **Use and Disclosures for Administrative and Internal Purposes.** Business Associate may use PHI for the proper management and administration of its business and to carry out the legal responsibility of Business Associate. Business Associate may disclose PHI for the proper management and administration of its business and to carry out the legal responsibility of Business Associate, provided the disclosures are required by law, or Business Associate obtains from any recipient of such PHI reasonable assurances that the PHI will remain confidential and be used or further disclosed as required by law or for the purposes for which it was disclosed and the recipient will notify Business Associate of any instances of which it is aware in which confidentiality of the PHI was breached.
 - (3) **Use for Data Aggregation Services.** Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B) and 164.501.
 - (4) **De-Identification Permitted by Law.** Business Associate may de-identify PHI as permitted by 45 C.F.R. § 164.514 and may use and disclose de-identified information, provided that any such use or disclosure shall be consistent with applicable law.
- B. **Compliance with Minimum Standard of Privacy Rule.** Business Associate agrees to comply with the minimum necessary standard for Business Associates as set forth in the Privacy Rule, 45 C.F.R. § 164.502(b).
- C. **Individual Authorization.** Business Associate may possess, use and disclose the PHI in any manner permitted consistent with a HIPAA-compliant authorization signed by or on behalf of the individual.

5. **Obligations of Covered Entity.**

- A. **Notification of Limitation in Notice of Privacy Practices.** Covered Entity shall notify Business Associate in writing of any limitations in its notice of privacy practices in accordance with 45 C.F.R. §164.520, to the extent that the limitations may affect Business Associate's use or disclosure of Protected Health Information.
- B. **Notification of Changes with Regard to Permissions Given by Individual.** Covered Entity shall notify Business Associate in writing of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that the changes or revocation may affect Business Associate's use or disclosure of Protected Health Information.
- C. **Notification of Restrictions on Use.** Covered Entity shall notify Business Associate in writing of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to or is required to abide by under 45 C.F.R. § 164.522, to the extent that the restriction may affect Business Associate's use or disclosure of Protected Health Information.
- D. **No Requests in Violation of HIPAA.** Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the HIPAA Rules, HIPAA or the HITECH Act if done by Covered Entity.
- E. **Duty to Minimize Disclosure.** Covered Entity shall use its best efforts to minimize the disclosure of Protected Health Information to Business Associate where the disclosure of that information is not needed for Business Associate to provide products or services to Covered Entity.

6. **Term and Termination.**

- A. **Term.** This Agreement shall be effective as of the date set forth above and it shall continue in effect until terminated as provided in Paragraphs 6.B or 6.C.
- B. **Termination.** This Agreement shall terminate when Business Associate no longer provides any Services set forth in any agreement with Covered Entity or on the date Covered Entity terminates this Agreement for cause as set forth below, whichever is sooner.
- C. **Termination for Cause.** If Covered Entity has reason to believe that Business Associate has violated a material term of this Agreement, Covered Entity shall notify Business Associate of the claimed violation and provide Business Associate with an opportunity to explain why no violation has occurred or to cure the violation. If Business Associate does not explain why no violation has occurred or cure the alleged violation within thirty (30) days after receiving Covered Entity's notice, Covered Entity may immediately terminate this Agreement by written notice to Business Associate.
- D. **Obligations upon Termination.** Upon termination of this Agreement for any reason, Business Associate with respect to all Protected Health Information received from Covered Entity, or created, maintained or received by Business Associate on behalf of Covered Entity, shall:
- (1) Retain only that PHI which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;

- (2) Return to Covered Entity or destroy, if feasible, the remaining PHI that Business Associate still maintains in any form, and if return or destruction is not feasible extend the protections of this Agreement to the PHI and limit further uses and disclosure to those purposes that make the return or destruction infeasible;
- (3) Continue to use reasonable safeguards, and comply, where applicable, with the Security Rule with respect to ePHI, to prevent use or disclosure of the PHI, other than as provided for in this Section of the Agreement, for as long as Business Associate retains the PHI;
- (4) Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set forth in Section 4(A)(2) above, which applied prior to termination; and
- (5) Return to Covered Entity or destroy, if feasible, the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities, and if return or destruction is not feasible extend the protections of this Agreement to the PHI and limit further uses and disclosure to those purposes that make the return or destruction infeasible.

7. **Notices.** Any notice required or permitted to be given hereunder shall be in writing and shall be (i) personally delivered, (ii) transmitted by postage pre-paid first class certified United States mail, (iii) transmitted by pre-paid, overnight delivery with delivery tracking service, or (iv) transmitted by facsimile transmission. All notices and other communications shall be deemed to have been duly given, received and effective on (i) the date of receipt if delivered personally, (ii) 3 business days after the date of posting if transmitted by mail, (iii) the business day after the date of transmission if by overnight delivery with proof of delivery, or (iv) if transmitted by facsimile transmission, the date of transmission with confirmation by the originating facsimile transmission machine of receipt by the receiving facsimile machine of such transmission, addressed to the Parties at the addresses below:

As to Covered Entity:	As to Business Associate:
To the address noted on the front of the Schedule	Carl Zeiss Meditec, Inc. Attn: Director, Data Privacy & Compliance Officer 5160 Hacienda Drive Dublin, CA 94568-7562

8. **Miscellaneous.**

- A. **Regulatory References.** A reference in this Agreement to a section in the HIPAA Rules, the Privacy Rule, the Security Rule, the Breach Notification Rule, HIPAA, or the HITECH Act means the section as in effect or as amended.
- B. **Amendment.** Upon the effective date of any final regulation or amendment to final regulations promulgated by HHS with respect to Protected Health Information, the HIPAA Rules, HIPAA, or the HITECH Act, this Agreement will automatically amend the obligations of Business Associate and Covered Entity to the extent necessary to remain in compliance with such regulations.
- C. **Assignment.** Neither party shall assign any of the rights granted by this Agreement nor delegate any of its duties under this Agreement without the prior written consent of the other party, except that either party may freely assign this Agreement to an affiliate, subsidiary, or other successor to that area of its business to which this Agreement is related that is controlled by, has control over, or is under common control with the assigning party. Subject to the limitations on assignment set forth in this paragraph, this Agreement will apply to, be binding in all respects upon, and inure to the benefit of, the successors and permitted assigns of the parties.
- D. **Choice of Law.** This Agreement shall be construed and interpreted, and the legal relations created hereby shall be determined, in accordance with the laws of the State of California, excluding those laws relating to choice of law and as if this Agreement were performed entirely within California.
- E. **Section Headings.** The Section headings used in this Agreement are for purposes of convenience or reference only. They shall not be used to explain, limit, or extend the meaning of any part of this Agreement.
- F. **Severability.** In the event that any one or more of the provisions contained in this Agreement shall for any reason be held by a court of competent jurisdiction to be unenforceable in any respect, such holding shall not affect any other provisions of this Agreement, and this Agreement shall then be construed as if such unenforceable provisions are not a part hereof.
- G. **Counterparts.** This Agreement may be executed in counterparts, any of which is considered to be an original agreement.
- H. **Survival.** Any provision of this Agreement, which by its terms is intended to survive the termination or expiration of this Agreement shall so survive.
- I. **Independent Contractors.** Covered Entity and Business Associate agree that the relationship between them is solely that of independent contractors and nothing in this Agreement is intended to create a partnership, agency, or joint venture between Covered Entity and Business Associate.
- J. **Entire Agreement.** This Agreement represents the entire agreement between the parties relating to the subject matter hereof, and

shall supersede any other agreements, whether written or oral. There are no understandings, representations, or warranties of any kind between the parties relating to the subject matter hereof, except as expressly set forth herein. No alteration or modification of any of the provisions of this Agreement shall be binding on any party unless in writing and signed by the party against whom enforcement of such alteration or modification is sought. Nothing in this Agreement shall be deemed to have amended or modified the terms or conditions of any other agreement between the parties, nor shall this Agreement be deemed to have created any rights or obligations except as specifically set forth in this Agreement.