**Business Associate Agreement Model**

**EXHIBIT C**

The Vision Council Optical Lab Division Legal Counsel has concluded that there are instances where an optical lab may need to have a Business Associate Agreement (BAA) with its vendors who provide services for and on behalf of the optical lab that involve the use and disclosure of PHI. For example, when the lab utilizes the services of a supplier of lab processing software, and that supplier accesses the lab’s PHI – either online or via backup tapes – for the purpose of software support and process control trouble shooting.

On the following pages is a model Business Associate Agreement that Optical Lab Division members of The Vision Council may use in this situation. The model agreement – with modifications – would also be applicable to other situations in which a lab might require a BAA.

It is the lab’s responsibility as the “covered entity” under HIPAA to secure this BAA with a lab software supplier, or other similar business associate.

**BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement (“B.A. Agreement”) is entered into by and between *[Optical Laboratory]* (“Covered Entity”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(“Business Associate”) as of this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_, 20\_\_ (“Effective Date”) .

**RECITALS**

WHEREAS, *[Optical Laboratory]* is a “Covered Entity” as defined under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) and its implementing regulations (collectively, “HIPAA”), as amended by the regulations promulgated pursuant to the Health Information Technology for Economic and Clinical Health (“HITECH”) Act (Division A, Title XIII and Division B, Title IV of Public L. 111–5) (which was part of the American Recovery and Reinvestment Act of 2009), and \_\_\_\_\_\_\_\_\_\_\_\_\_ is a “Business Associate” as defined under HIPAA; and

WHEREAS, in connection with the *[services]* agreement between Covered Entity and Business Associate for Business Associate to provide *[certain services]* for and on behalf of Covered Entity (the “Agreement”), Covered Entity may provide Business Associate with Protected Health Information (defined below); and

WHEREAS, Covered Entity and Business Associate intend to protect the privacy and provide for the security of PHI disclosed to Business Associate pursuant to this BAA, which is drafted to satisfy specific components of HIPAA and relevant implementing regulations, including the Privacy Rule (defined below), the Security Rule (defined below) and the Breach Notification Rule (defined below).

**I. DEFINITIONS**

(a) “Breach” shall have the meaning given to such term in 45 C.F.R. § 164.402 and applicable State data breach notification law.

(b) “Breach Notification Rule” shall mean the rule related to breach notification for Unsecured Protected Health Information at 45 C.F.R. Parts 160 and 164.

(c) “Designated Record Set” shall have the meaning given to such term under the Privacy Rule at 45 C.F.R. § 164.501.

(d) "Electronic Protected Health Information" or ("EPHI") shall have the same meaning given to such term under the Security Rule, including, but not limited to, 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity..

(e) “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information, codified at 45 C.F.R. Parts 160 and Part 164, Subparts A and E.

(f) “Protected Health Information” or “PHI” shall have the meaning given to such term under the Privacy and Security Rules at 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(g) “Security Rule” shall mean the Security Standards for the Protection of Electronic Protected Health Information, codified at 45 C.F.R. § 164 Subparts A and C.

(h) Other capitalized terms used, but not otherwise defined, in this B.A. Agreement shall have the same meaning as those terms in the Privacy, Security or Breach Notification Rules.

**II. PRIVACY RULE****OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE**

(a) Limitations of Disclosures. Business Associate agrees to not use or disclose PHI other than as permitted or required by this B.A. Agreement or, the Agreement, or as Required By Law. Business Associate shall not use or disclose PHI in a manner that would violate the Privacy Rule if done by Covered Entity, unless expressly permitted to do so pursuant to the Privacy Rule, the Agreement, and this B.A. Agreement.

(b) Appropriate Safeguards. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as permitted by this B.A. Agreement, the Agreement, or as Required By Law.

(c) Obligations on Behalf of Covered Entity. To the extent Business Associate carries out an obligation for which Covered Entity is responsible under the Privacy Rule, Business Associate must comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligation.

(d) Mitigation. Business Associate shall 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 HIPAA, the Agreement, or this B.A. Agreement.

(e) Reporting of Improper Use or Disclosure. Business Associate agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this B.A. Agreement within five (5) days of which it becomes aware.

(f) Business Associate’s Subcontractors. Business Associate agrees to ensure that any Subcontractor, consistent with 45 C.F.R. § 164.502(e)(1)(ii), that creates, receives, maintains, or transmits PHI on behalf of Business Associate agrees in writing to the same restrictions and conditions that apply through this B.A. Agreement to Business Associate with respect to such PHI.

(g) Access to PHI. Business Associate shall provide access, at the request of Covered Entity, and in the time and manner reasonably designated by Covered Entity, to PHI in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual or a third party designated by the Individual, in order to meet the requirements under the Privacy Rule at 45 C.F.R. § 164.524.

(h) Amendment of PHI. Business Associate shall make any PHI contained in a Designated Record Set available to Covered Entity (or an Individual as directed by Covered Entity) for purposes of amendment per 45 C.F.R. § 164.526. Business Associate shall make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to the Privacy Rule, at the request of Covered Entity, and in the time and manner reasonably designated by Covered Entity. If an Individual requests an amendment of PHI directly from Business Associate or its Subcontractors, Business Associate shall notify Covered Entity in writing within five (5) days of receiving such request. Any denial of amendment of PHI maintained by Business Associate or its Subcontractors shall be the responsibility of Covered Entity.

(i) Government Access to Records. Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI, available to the Secretary, in a time and manner designated by the Secretary, for determining Covered Entity’s compliance with the Privacy Rule.

(j) Documentation and Accounting of Disclosures. Business Associate agrees to document such disclosures of PHI 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 PHI in accordance with 45 CFR 164.528. Business Associate agrees to provide to Covered Entity, in time and manner requested by Covered Entity, information collected in accordance with this paragraph, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(k) Retention of PHI. Notwithstanding Section VI(c) below, Business Associate and its Subcontractors shall retain all PHI throughout the term of the Agreement and shall continue to maintain the information required under Section II(j) for a period of six (6) years after termination of the Agreement.

(l) Minimum Necessary. Business Associate shall only request, use and disclose the Minimum Necessary amount of PHI necessary to accomplish the purpose of the request, use or disclosure.

**III. PERMITTED USES AND DISCLOSURES OF PHI BY BUSINESS ASSOCIATE**

(a) Permitted Uses and Disclosures of PHI. Except as provided in Paragraphs (b), (c), and (d) of Section III, Business Associate may only use or disclose PHI to perform functions, activities or services for, or on behalf of Covered Entity, as specified in the Agreement.

(b) Use for Management and Administration. Except as otherwise limited in this B.A. Agreement, Business Associate may, consistent with 45 C.F.R. 164.504(e)(4), use PHI if necessary (i) for the proper management and administration of Business Associate, or (ii) to carry out the legal responsibilities of Business Associate.

(c) Disclosure for Management and Administration. Except as otherwise limited in this B.A. Agreement, Business Associate may, consistent with 45 C.F.R. 164.504(e)(4), disclose PHI for the proper management and administration of Business Associate, provided (i) the disclosure is Required by Law, or (ii) Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed (“Person”) that it will be held confidentially and will be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the Person, and that the Person agrees to immediately notify Business Associate in writing of any instances of which it becomes aware in which the confidentiality of the information has been breached or is suspected to have been breached.

(d) Reporting Violations. 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).

**IV. SECURITY RULE OBLIGATIONS OF BUSINESS ASSOCIATE**

(a) Compliance with the Security Rule. Business Associate agrees to comply with the Security Rule with respect to Electronic Protected Health Information and have in place reasonable and appropriate Administrative, Physical, and Technical Safeguards to protect the Confidentiality, Integrity, and Availability of EPHI and to prevent the use or disclosure of EPHI other than as permitted by the Agreement, this B.A. Agreement, and as Required By Law.

(b) Subcontractors. Business Associate shall ensure that any Subcontractor that creates, receives, maintains, or transmits EPHI on behalf of Business Associate agrees in writing to comply with the Security Rule with respect to such EPHI.

(c) Security Incident/Breach Notification Reporting. Business Associate shall report any Security Incident promptly upon becoming aware of such incident. Separate from the requirements related to Security Incident reporting, Business Associate shall also make the reports set forth below in Section V, related to a Breach of Unsecured PHI.

**V. BREACH NOTIFICATION (FEDERAL AND STATE) RULE OBLIGATIONS OF BUSINESS ASSOCIATE**

(a) Notification Requirement. Immediately following Business Associate’s discovery of a Breach, or upon Business Associate’s reasonable belief that a Breach has occurred, Business Associate shall provide written notification of such Breach to Covered Entity.

(b) Discovery of Breach. For purposes of reporting a Breach to Covered Entity, the discovery of a Breach shall occur on the first day on which such Breach is known to Business Associate or, by exercising reasonable diligence, would have been known to or suspected by the Business Associate. Business Associate will be considered to have had knowledge of a Breach if the Breach is known, or by exercising reasonable diligence would have been known to any person (other than the person committing the Breach) who is an employee, officer or agent of the Business Associate.

(c)Content of Notification. Any notice referenced above in Section V(a) of this B.A. Agreement will include, to the extent known to the Business Associate, 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 the information, to the extent known by Business Associate, that Covered Entity is required to include in its notification to the individual pursuant to the Breach Notification Rule or applicable State data breach notification laws. Business Associate will also provide (on a continuing basis as information is discovered) to Covered Entity other available information that Covered Entity is required to include in its notification to the individual pursuant to the Breach Notification Rule or applicable State data breach notification laws.

(d) Cooperation with Covered Entity. Business Associate shall:

(i) Cooperate and assist Covered Entity with any investigation into any Breach or alleged Breach, including those conducted by any Federal agency, State Attorney General, State agency (or their respective agents);

(ii) Comply with Covered Entity’s determinations regarding Covered Entity’s and Business Associate’s obligations to mitigate to the extent practicable any potential harm to the individuals impacted by the Breach; and

(iii)As directed by the Covered Entity, assist with the implementation of any decision by Covered Entity or any Federal agency, State agency, including any State Attorney General, or their respective agents, to notify and provide mitigation to individuals impacted or potentially impacted by a Breach.

**VI. TERM AND TERMINATION**

(a) Term. The term of this B.A. Agreement shall commence as of the Effective Date, and shall terminate when 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, or, if it is infeasible to return or destroy the PHI, protections are extended to such information, in accordance with the provisions of this Section VI.

(b) Termination for Cause. Upon Covered Entity’s knowledge of a material breach of the terms of this B.A. Agreement, Covered Entity shall:

(i) Provide an opportunity for Business Associate to cure, and, if Business Associate does not cure the breach within thirty (30) days, Covered Entity may immediately terminate this BAA and the Agreement;

(ii) Immediately terminate this BAA and the Agreementif Covered Entity has determined that (a) Business Associate has breached a material term of this BAA, and (b) cure is not possible; or

(iii) Immediately terminate this BAA if the Agreement has been terminated.

(c) Effect of Termination.

(i) Except as provided for in paragraph (ii) of this Section VI(c), upon termination of this B.A. 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, and shall not retain copies thereof. This provision shall apply to PHI that is in the possession of Subcontractors of Business Associate.

(ii) In the event that Business Associate and Covered Entity determine, by mutual agreement, that returning or destroying the PHI is infeasible, Business Associate shall extend the protections of this B.A. 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.

**VII. MISCELLANEOUS**

(a)Regulatory References. A reference in this B.A. Agreement to a section in the Privacy, Security, or Breach Notification Rule means the section as in effect or as amended, and for which compliance is required.

(b) Survival. The respective rights and obligations of Business Associate under Section 6(c) of this BAA shall survive the termination of the BAA.

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

(d) Amendment. The parties agree to take such action as is necessary to amend this B.A. Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy, Security or Breach Notification Rules, as well as HIPAA and HITECH.

(e) Effect on Agreement. Except as specifically required to implement the purposes of this B.A. Agreement, or to the extent inconsistent with this B.A. Agreement, all other terms of the Agreement shall remain in force and effect.

(f) Interpretation. The provisions of this B.A. Agreement shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provision in this B.A. Agreement. Any ambiguity in this B.A. Agreement shall be resolved to permit Covered Entity to comply with the Privacy, Security, and Breach Notification Rules, as well as HIPAA and HITECH.

(g) Disclaimer. Covered Entity makes no warranty or representation that compliance by Business Associate with this B.A. Agreement is satisfactory for Business Associate to comply with any obligations it may have under HIPAA, the Privacy Rule, or any other applicable law or regulation pertaining to the confidentiality, use or safeguarding of health information. Business Associate is solely responsible for all decisions it makes regarding the use, disclosure or safeguarding of PHI.

(h) Indemnification.

(i) Business Associate shall indemnify, defend and hold Covered Entity and its officers, directors, employees, agents, successors and assigns (“Covered Entity Indemnitees”) harmless, from and against any and all losses, claims, actions, demands, liabilities, damages, costs and expenses (including, but not limited to, costs of providing notifications and credit monitoring services to individuals pursuant to the Breach Notification Rule and State data breach notification laws, administrative costs associated with Covered Entity’s and Business Associate’s compliance with Breach Notification Rule and State data breach notification laws, judgments, settlements, court costs and reasonable attorneys’ fees actually incurred) (collectively, “Information Disclosure Costs”) arising from or related to: (1) any breach of this BAA by Business Associate, including but not limited to the use or disclosure by Business Associate of Individually Identifiable Information (including PHI) in violation of the terms of this B.A. Agreement or applicable law; and (2) whether in oral, paper or electronic media, any Breach caused, directly or indirectly, by Business Associate.

(i) Counterparts. This B.A. Agreement may be executed in multiple counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Facsimile or electronic (PDF) signatures shall be treated as original signatures. This B.A. Agreement shall be binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all of the parties reflected on this B.A. Agreement as the signatories thereto.

***[Optical Laboratory]*: *[Business Associate]*:**

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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