**RESEARCH COLLABORATOR AGREEMENT**

This RESEARCH COLLABORATION AGREEMENT (“**Agreement**”) is made as of last date of signature (the “**Effective Date**”) by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“**Research Collaborator**”) and Apple Tree Dental, a non-profit dental practice group with its principal place of business at 2442 Mounds View Blvd, Mounds View, Minnesota, 55112, hereinafter referred to as **“Apple Tree”**. Each of Research Collaborator and APPLE TREE may be referred to herein as a **“Party”** or collectively as the **“Parties”**.

RECITALS

**WHEREAS**, Research Collaborator is a non-profit, tax-exempt medical research organization engaged in scientific research and educational activities.

**WHEREAS**, conducting research furthers the instructional and research objectives of APPLE TREE in a manner consistent with its status as a non-profit research, educational and health care provider;

**WHEREAS**, the Parties wish to enter into this Agreement to establish the terms and conditions under which APPLE TREE will provide patient data and data processing methodologies to Institute for the purpose of a research project, and how Institute will use and disclose such data.

**NOW THEREFORE**, in consideration of the mutual covenants contained herein and intending to be legally bound, the Parties agree as follows:

**Article 1. Statement Of Work.**

The Parties, through the Research Collaborator Principal Investigator and the APPLE TREE Principal Investigator (as defined below), agree to use reasonable efforts to perform the research project described in Exhibit A (the “Research Project”) using limited data sets provided by APPLE TREE which are described in Exhibit B (“DATA”).

**Article 2. Principal Investigator(s).**

The Research Project will be supervised by \_\_\_\_\_\_\_\_\_ (the “Research Collaborator Principal Investigator”) from the Research Collaborator and Lyubov Slashcheva, DDS, MS from APPLE TREE (the “APPLE TREE Principal Investigator”). If, for any reason, the Principal Investigator is unable to serve, and a successor acceptable to both Research Collaborator and APPLE TREE is not available, this Agreement may be terminated as provided in Article 3.

**Article 3. Term/Termination.**

3.1 Term. The term of this Agreement shall begin on the Effective Date and, subject to Article 5 below, shall remain in effect for twelve (12) months, unless terminated earlier pursuant to the terms of this Agreement. It may be renewed for an additional term to be stipulated then as agreed upon in writing by both Parties. However, Research Collaborator shall have no liability to APPLE TREE, nor shall it be in default under this Agreement, if Institute’s performance is delayed or prevented by any cause beyond Research Collaborator’s control.

3.2 Termination.

1. This Agreement may be terminated at any time without cause by either Party with thirty (30) days' prior written notice to the other Party.
2. A breach by Research Collaborator of any provision of Article 7 of this Agreement shall constitute a material breach and grounds for immediate termination by APPLE TREE, provided that APPLE TREE shall give Institute 30 days to cure any such breach.

C. The Parties agree that either Party may immediately terminate this Agreement if the other Party breaches any provision of Exhibit D (Business Associate Agreement).

**Article 4. Collaboration Costs and Expenses.**

4.1 To support the conduct of the Project, Institute shall pay the costs that it incurs and the costs specifically incurred by APPLE TREE in conducting the Project. More specifically, Institute will pay or reimburse APPLE TREE the direct and indirect costs as described in the budget for the Project, which is attached hereto and incorporated herein as Exhibit E (“Budget”). Research Collaborator shall make such payments to APPLE TREE in accordance with the payment schedule specified in the Budget. Notwithstanding the foregoing or any other provision of this Agreement, in no event shall Research Collaborator be obligated to pay or reimburse APPLE TREE any amount in excess of \_\_\_\_\_ US Dollars (US$ \_\_\_\_\_).

**Article 5. Ownership and Publication.**

5.1 Report/Protocol/DATA. APPLE TREE shall retain all rights to the DATA collected and analyzed as a result of the Research Project, which shall be owned solely by APPLE TREE. APPLE TREE hereby grants Research Collaborator a worldwide, non-exclusive, royalty-free license to use the DATA collected, analyzed or generated as a result of the Research Project for any and all research purposes.

5.2  Publication.

* 1. Subject to the terms of this Agreement, publication rights related to the Research Project shall be co-owned.
  2. The Parties agree to explore mutually advantageous co-publishing opportunities.
  3. In the event either Party wants to pursue an independent publication:
     1. The publishing Party agrees to provide a copy of the proposed publication to the other Party for review and comment at least thirty (30) days prior to submission.
     2. Both Parties will give due consideration to the other Party’s comments and will acknowledge the other Party in such publications in accordance with scientific standards.
     3. Notwithstanding the foregoing, neither Party will disclose the other Party’s Confidential Information (as defined in Section 6.1 of this Agreement) in any publication, and the publishing Party agrees to remove any Confidential Information of the non-publishing Party from any such publication.
  4. Both Parties shall retain all rights to their independent publications.
  5. This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the DATA.
  6. The Research Collaborator agrees to provide appropriate acknowledgement of the source of the DATA in all independent publications.

5.3  Pre-Existing Intellectual Property. Existing inventions, ideas, discoveries, technologies and

methodologies of each Party that are owned by or licensed to such Party prior to the Effective Date or developed by such Party outside the scope of the Research Project (the “Background IP”) are their separate property, whether or not protected by patent or other intellectual property rights, and are not affected by this Agreement. Neither Party shall have any claims to or rights to the Background IP of the other Party.

5.4 Inventions.

A. The Parties do not intend for the conduct of the Research Project to result in the development of any new inventions or discoveries (“Inventions”). In the event the Parties intend to engage in activities which may result in the development of Inventions, or the Research Project does result in the development of Inventions, the Parties agree to negotiate in good faith mutually acceptable ownership rights and licenses to such Inventions.

1. It is expressly agreed that neither APPLE TREE nor Research Collaborator shall transfer by operation of this Agreement to the other Party hereto any patent right, copyright, or other proprietary right that either Party owns as of the commencement of this Agreement, except as specifically set forth herein.
2. A written disclosure of any invention that arises from the performance of the Research Project (“Invention”) shall be promptly provided to one Party by the other Party. The non- disclosing Party shall maintain all such disclosures in confidence and shall not deliver or divulge them to any person. Inventorship of any Invention shall be determined in accordance with U.S. patent law, and ownership shall follow inventorship.
3. If an Invention is solely owned by one Party (the “Owning Party”), the other Party shall have no further rights to such Invention, other than being granted a non-exclusive, fully paid license, without the right to sublicense, to use such Invention for its internal non- commercial research and teaching purposes only.
4. If an Invention is jointly owned by both Parties, upon receiving such Invention disclosure, the Parties shall promptly undertake negotiations in good faith for an arrangement to govern the protection and exploitation of such Invention, taking into consideration the relative contributions of the Parties in developing such Invention. If within ninety (90) days from the Invention disclosure, the Parties are not in active negotiation with respect to such Invention, Research Collaborator and APPLE TREE shall each retain its own rights, title and interest and shall each be free to practice, enforce, license, assign its interest in, and exploit commercially any such joint Invention independently of each other, and authorize others to do so, with no obligation to obtain consent of the other or to account to the other for profits or otherwise.
5. APPLE TREE hereby grants to Research Collaborator a right of first negotiation to negotiate an exclusive license with respect to any Invention for which APPLE TREE is the Owning Party. Within ninety (90) days of an Invention disclosure pursuant to Section 5.4(C) above, Research Collaborator shall advise APPLE TREE of its decision to exercise this option. If Research Collaborator exercises the option, APPLE TREE shall negotiate exclusively with Research Collaborator with respect to such Invention for a period of ninety (90) days following Research Collaborator’s request (the “Negotiation Period”). If the Parties do not reach agreement with respect to a term sheet within such Negotiation Period, APPLE TREE will be free to grant rights to the Inventions to a third party.

5.5 Survival. This section shall survive the termination or expiration of this Agreement.

**Article 6. Confidentiality.**

6.1 Confidential Information. Each Party (in such capacity receiving information, the “Receiving Party”) agrees to hold in confidence all materials, documents and information disclosed to it by the other Party (in such capacity disclosing information, the “Disclosing Party”) pursuant to this Agreement, including, without limitation, information relating to identified patients and/or study subjects whose identities may be ascertained by the exercise of reasonable effort through investigation or through use of other public or private databases; scientific techniques, designs, drawings, processes, inventions, developments, equipment, and prototypes; sales and customer information; and business and financial information, relating to its business, products, practices or techniques (“Confidential Information”).

6.2 Permitted Disclosures of Confidential Information. Except as provided herein, neither Receiving Party will disclose Confidential Information of Disclosing Party to any third party without prior written consent from the Disclosing Party, except that Receiving Party may disclose Disclosing Party’s Confidential Information to its agents, attorneys, consultants, and affiliates who have a “need to know” such information for purposes of the Research Project and who are bound to confidentiality obligations at least as protective of Disclosing Party and its Confidential Information as the terms set forth in this Agreement. All Confidential Information shall be returned to the Disclosing Party promptly after the termination or expiration of this Agreement or upon the Disclosing Party’s earlier request, provided, however, each Receiving Party may retain one (1) copy of the Disclosing Party’s Confidential Information in its secure archives as necessary for purposes of meeting applicable professional standards and/or legal requirements. Research Collaborator retains the right to refuse to accept any such information which is not considered to be essential to the completion of the Research Project.

6.3 Exceptions to Confidential Information. The Receiving Party’s obligations of this section shall not apply to: (i) information which is or becomes public, except through breach of this Agreement by Receiving Party; (ii) information which is known or becomes known to Receiving Party independently from this Agreement from a third party with the legal right to disclose such information; (iii) information which is received from a third party which was not prohibited from disclosing such information; or (iv) information which is required by law to be disclosed, provided that the Disclosing Party is notified of any such requirement with sufficient time (if possible) to seek a protective order or other modifications to the requirement, and further provided that the Receiving Party reasonably assist the Disclosing Party in seeking any such protective order or other modifications.

6.4 Survival of Confidential Information Obligations. Each Receiving Party’s obligations under this Article shall survive and continue for five (5) years after termination or expiration of the Agreement.

**Article 7. DATA**

7.1. APPLE TREE and Research Collaborator agree to collaborate to ensure DATA is provided and analyzed in full compliance with all applicable Federal, State and Local provisions, including, as required by law, securing such agreements as a Business Associate Agreements (BAA) (attached hereto Exhibit D and referenced in Article 8 below), and Institutional Review Board (IRB) approvals, as required.

7.2. APPLE TREE retains ownership of the DATA. Research Collaborator acknowledges that Research Collaborator has no ownership rights in the DATA.

7.3. Research Collaborator shall ensure that all persons/corporations to whom the DATA is disclosed agrees in writing to the same restrictions and conditions regarding the DATA that apply to Research Collaborator under this Agreement.

7.4. Research Collaborator must implement reasonable and appropriate safeguards to prevent the use and disclosure of the DATA in any manner not permitted by this Agreement and/or the BAA.

7.5. Research Collaborator must notify APPLE TREE in accordance with the terms contained in the BAA attached hereto as Exhibit D.

7.6.  DATA may be used by either Party for any and all research purposes.

7.7.  DATA is not to be used for commercial purposes by the Research Collaborator and/or the Research Collaborator Principal Investigator without prior written consent from APPLE TREE.

If the Research Collaborator desires to use or license the DATA for commercial purposes, then the Research Collaborator agrees, in advance of such use, to negotiate in good faith with APPLE TREE to establish the terms of a commercial license. It is understood by the Institute that APPLE TREE shall have no obligation to grant such a license to the Research Collaborator, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the DATA to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

7.8.  DATA will not be transferred to anyone else without the prior written consent of APPLE TREE.

7.9.  The restrictions and responsibilities of Institute under this Agreement shall survive termination of this Agreement.

7.10. Unless specifically stated otherwise in this Agreement, Research Collaborator’s obligations with respect to the DATA apply to the whole and to any part of the DATA regardless of method of transmission (electronic or otherwise).

7.11. Research Collaborator must implement reasonable and appropriate Administrative, Physical, and Technical Safeguards (collectively the “Safeguards”) to prevent the use and disclosure of the DATA in any manner not permitted by this Agreement. Such safeguards shall include (but not be limited to) those safeguards provided by the Laws and Regulations.

7.12 Research Collaborator and the Research Collaborator Principal Investigator agree that capitalized

A. That capitalized terms used herein are defined within this agreement or in 45 CFR Parts 160, 162 and 164 (the “Privacy Rule” and the “Security Rule”) and the HITECH Act. The Privacy Rule, Security Rule, HITECH Act and any other federal or state laws regulating the use and/or disclosure of patient data are herein collectively referred to as “Laws and Regulations.”

B. For purposes of this Section 7.12, **DATA** means the data elements listed in **Exhibit B** have been de-identified of all Protected Health Information (“**PHI**”) as defined in the Laws and Regulations.

C. Research Collaborator shall not use or disclose the DATA for any purpose other than the Study or as required by Laws and Regulations and such use/disclosure will be in accordance with Article 7 and Exhibits B and D. In addition, Institute shall not use or disclose the DATA in any manner that would violate the Business Associate Agreement (“BAA”) attached hereto as Exhibit D or any Laws and Regulations if done by APPLE TREE.

D. Research Collaborator shall ensure that all persons/corporations to whom the DATA is disclosed agrees in writing to the same restrictions and conditions regarding the DATA that apply to Research Collaborator under this Agreement and the BAA.

**Article 8. Business Associates.**

The Parties hereto agree that the Parties must meet the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA) and Title XIII of the American Recovery and Reinvestment Act of 2009 (“ARRA”) also known as the Health Information Technology for Economic Clinical Health Act (the “HITECH Act”) for a Business Associate Agreement. The Parties further agree to abide by the terms of such Business Associate Agreement, attached hereto and incorporated herein as **Exhibit D**.

**Article 9. Reports.**

Each Principal Investigator will update the other Principal Investigator, in reasonable detail, on the progress of the Research Project on a periodic basis. If reasonably requested by either Party, within sixty (60) days after the expiration or termination of this Agreement, the other Party shall submit to requesting Party a final written technical report of all activities undertaken and all accomplishments achieved in connection with the Research Project.

**Article 10. Indemnification.**

Each Party agrees to defend, indemnify, and hold harmless the other Party and their agents, employees, directors and affiliates from and against any and all damages, liabilities and costs (including attorneys' fees), arising from claims and suits brought by third parties (except for claims brought by one Party against the other Party as required by HIPAA) arising from the indemnifying Party’s: (i) use, non-use, interpretation or disclosure of DATA; (ii) violation of any third party’s trade secrets; (iii) breach of this Agreement or BAA; (iv) violation of any law or regulation; or (v) negligent or intentional acts by itself or its employees, agents, consultants, or subcontractors. Said indemnity is in addition to any other rights that the indemnified Party may have against the indemnifying Party and will survive the termination of this Agreement. Any Party seeking indemnification pursuant to Article 10 shall: (i) give the indemnifying Party prompt notice of any such claim or lawsuit (including, if allowable by law, a copy thereof) served upon it with respect to which such indemnified Party intends to claim such indemnification; (ii) give the indemnifying Party sole control of the defense and/or settlement (subject to the terms of this section) thereof; and (iii) fully cooperate with the indemnifying Party and its legal representatives in the investigation of any matter the subject of which impacts indemnification. The indemnifying Party shall not settle any such claim, suit or proceeding or otherwise consent to an adverse judgment in such claim, suit or proceeding if the same materially diminishes the rights or interests of the indemnified Party without the express written consent of such indemnified Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, the indemnifying Party shall have no obligations for any claim, suit or proceeding if the indemnified Party seeking indemnification makes any admission, settlement or other communication regarding such claim, suit or proceeding, without the prior written consent of the indemnifying Party, which consent shall not be unreasonably withheld.

**Article 11. Independent Entities.**

None of the provisions of this Agreement shall be deemed or construed to create any relationship between the Parties other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. None of the Parties have any express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other Party, except as may otherwise be set forth in this Agreement. This Agreement is not a “work-for-hire” agreement under the copyright laws of any country.

**Article 12. General Provisions**

The Parties agree to abide by the terms set forth in Exhibit C, which is attached hereto and incorporated herein by this reference.

**Article 13. No Warranty**

THE PARTIES UNDERSTAND, ACKNOWLEDGE AND AGREE THAT NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, IS MADE REGARDING EITHER PARTY’S RESEARCH ACTIVITIES, WORK PRODUCT, ACTIVITIES OR SERVICES PROVIDED PURSUANT TO THE TERMS AND CONDITIONS OF THIS AGREEMENT.

**Article 14. Notices**

Except for those notices provided pursuant to Exhibit D (Business Associate Agreement) which are subject to the Notice provision included in said Business Associate Agreement, all other notices and communications related to this Agreement must be in writing and will be deemed given: (i) when personally delivered, (ii) upon confirmation of a facsimile transmittal, or (iii) upon receipt when deposited with the United States Postal Service, postage prepaid, addressed as follows or to such other person, fax and/or address as the party to receive may designate by notice to the other:

**If to Research Collaborator:**

Contact Information

**If to APPLE TREE:**

Apple Tree Dental  
Corporate Office  
2442 Mounds View Blvd  
Mounds View, Minnesota 55112 Attention: Michael Helgeson, CEO

**Article 15. Amendment/Entire Agreement/Multiple Originals**

15.1 If either Party reasonably concludes that an amendment to this Agreement is necessary to comply with applicable Laws and Regulations, such Party shall notify the other Party in writing of the proposed modification(s) (“Legally-Required Modifications”). The Parties shall work together in good faith to negotiate an amendment to this Agreement in light of such Legally-Required Modifications. If the Parties are unable to agree upon such an amendment within thirty (30) days, either Party may terminate this Agreement upon written notice to the other Party.

15.2 This Agreement, together with any attachments or exhibits, sets forth the entire Agreement between the Parties with respect to the subject matter hereof. Any prior agreements, promises, negotiations, or representations, whether oral or written, not expressly set forth in this Agreement, are of no force or effect. Except as otherwise expressly stated herein, this Agreement may not be amended except by a writing signed by both Parties. This Agreement shall be executed in multiple originals (in written, facsimile, or electronic (e.g., PDF) form), one (1) for each of the Parties hereto, each of which, shall together, constitute and be one and the same instrument.

**The undersigned** represent that they are duly authorized to execute this Agreement on behalf of the Party for whom they sign; and such Party shall be bound by the terms of this Agreement.

Research Collaborator Apple Tree Dental

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Exhibit A**

Statement Of Work

* 1. Research Proposal Title
  2. Contents
  3. Specific Aims Summary
  4. Introduction
  5. Barriers and Opportunities
  6. Background and Approach
     1. Data Preparation and Analysis Plan
        1. Data Source
        2. Data Analysis
  7. Research Design and Methodology (per aim)
     1. Research Approach
     2. Research Questions and Hypotheses
     3. Cohort Development
     4. Areas of Study
     5. Data Sources
  8. Partnership and Collaboration
     1. Table with role distributions
  9. Timelines and Deliverables
  10. Potential Limitations and Barriers
  11. Dissemination and Implementation Plan
  12. Team Qualifications
  13. References
  14. Addendums
      1. Data set samples
      2. Preliminary data analyses

**Exhibit B**

Data

1. Data set description
2. Data processing methodologies
   1. Data processing used by APPLE TREE will include standard procedures for data extraction, transformation and loading (ETL) and best practices for de-identification, normalization and secure transfer.
3. Permitted users
   1. The data can be used only for the purposes described in the Statement of Work as described in Exhibit A.
4. Permitted disclosures
   1. The DATA should not be used or disclosed for any purposes other than what is described in the Statement of Work.
5. Data sub-users (consultants)
   1. The following Data Managers or agents of Collaborator may use or receive the DATA in the course of assisting Collaborator in the performance of its obligations under the Agreement: See Collaborator Consultants under Exhibit E.
6. Data protection
   1. Study staff and the Institute study team will have access to a data set provided by APPLE TREE. Any data will be stored in Collaborator Data Science Cloud hosted by HIPAA-compliant AWS. With controlled access to only member of the study team.
7. Data destruction/retention
   1. At the end of the Study, Institute will destroy all data and provide notice in writing to APPLE TREE once DATA has been destroyed. Pursuant to the Research Project, the DATA must be destroyed within 30 business days of completion of the Research Project.

**Exhibit C**

General Provisions

1. **Assignment.** Neither this Agreement nor any portion of this Agreement may be assigned or delegated by any Party without the prior written consent of the other Party unless: (i) to a successor to all or substantially all of its business or assets to which this Agreement pertains, whether by merger, consolidation, reorganization, operation of law or otherwise; provided such party is located in the United States, or (ii) upon thirty (30) days prior written notice, assigned or delegated to a party controlled by, in control of, or under common control with the assigning Party; provided such party is located in the United States. Any purported assignment or delegation in violation of this section is void. This Agreement binds and benefits the Parties and their permitted successors and assigns.
2. **Certification of Debarment.** The Parties certify, to the best of their knowledge and belief, after due inquiry using industry standards, that the Parties and/or any of their principals: (i) are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency; and (ii) have not been convicted of a criminal offense related to the provision of health care items or services. Industry standards shall include, but not be limited to, performing regular exclusion checks on federal and state exclusion databases for its employees, agents and contractors performing its duties under this Agreement. Upon request, each Party shall provide the other Party documentation evidencing such completed exclusion checks and compliance with this Section. During the term of this Agreement, each Party shall provide immediate written notice to the other Party if such Party learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. In the event either Party's certification is or becomes erroneous, the other Party may terminate this Agreement immediately upon notice.
3. **Compliance.** During the term of this Agreement, the Parties agree to comply with any and all laws, rules, regulations, licensing requirements or standards that are now or hereafter promulgated by any local, state, and federal governmental authority/agency or accrediting/administrative body that governs or applies to their respective duties and obligations hereunder (the “Applicable Laws and Standards”). The Applicable Laws and Standards shall include, but not be limited to, state and federal privacy and security laws related to the use and disclosure of health and medical information, the requirements of the Department of Health ("DOH"), The Joint Commission and the National Committee on Quality Assurance ("NCQA"), as applicable. Neither Party will, at any time, remunerate the other Party directly or indirectly for the referral, the inducement of a referral, or for the arranging of a referral of a Medicare or Medicaid patient. Nothing in this Agreement is intended to require or induce any Party to refer any Medicare or Medicaid patient to the other parties.
4. **Construction of Agreement.** The Parties acknowledge that they have thoroughly reviewed this Agreement and bargained over its terms in an arm’s length process. Accordingly, this Agreement shall be construed without regard to the Party or Parties responsible for its preparation, and shall be deemed to have been prepared jointly by the Parties. All titles of articles or sections under this Agreement are solely for convenience and do not constitute a substantive part of this Agreement. Words importing the singular include the plural and vice versa. Words importing one gender include both genders.
5. **Governing Law.** The laws of the state of Delaware (without giving effect to its conflicts of law principles) govern all matters arising out of or relating to this Agreement. The federal or state courts located in the state of Delaware shall have jurisdiction over all matters arising out of or relating to this Agreement.
6. **Insurance.** Each Party agrees to maintain during the term of this Agreement, at its own cost and expense, insurance coverage in amounts consistent with industry standards and necessary and reasonable to insure itself and its employees and agents against any claims of any nature, which may arise from performance of its duties and responsibilities under this Agreement. If any such insurance coverage is on a “claims-made basis”, in the event the policy expires or is terminated, “tail coverage” must be purchased to cover any subsequent claims based on acts or omissions that occurred during the term of this Agreement. Upon request, each Party agrees to provide the other Party with a Certificate of Insurance evidencing said insurance covering such liability with an insurer AM Best rated A or better or through a qualified self-insurance program. Further, the Parties agree to notify one another immediately if the aggregate coverage as stated on the Certification of Insurance is impaired more than fifty percent (50%).
7. **Medicare Access to Records.** To the extent required by law, if the services provided under this Agreement pursuant to the Research Project have a cost or value of $10,000 or more over a twelve (12) month period, the Parties agree to preserve and provide access to each one's contracts, books, documents, and records to the Comptroller General of the United States, Health and Human Services, and their duly authorized representatives until the expiration of four (4) years after the termination of the Research Project under this Agreement or as may be provided by regulation from time to time to implement the provisions of the Social Security Act relating to the determination of reasonable costs as a provider of, or a subcontractor of, services under the Medicare program.
8. **No Waiver.** A delay or omission by a Party to exercise any right under this Agreement shall not be construed to be a waiver of such right. No waiver by any Party of a breach of this Agreement will be deemed a waiver of any subsequent breach.
9. **Nondiscrimination.** Each Party agrees to comply with all applicable Federal, state and local laws respecting discrimination. The Parties hereby incorporate the requirements of 41 C.F.R. § 60-1.4(a), 41 C.F.R. § 60-741.5(a), 41 C.F.R. § 60-250.5(a), 41 C.F.R. § 60-300.5(a), and 29 C.F.R. § 471 Appendix A to Subpart A (Executive Order 13496), as applicable.
10. **Notification of Incidents.** Each Party agrees to promptly notify the other Party after the discovery of any incidents, occurrences, claims, or other causes of action involving this Agreement. The Parties agree to cooperate with each other as may be necessary to resolve such matters. Notwithstanding the above, neither of the Parties shall be required to provide the other Party with copies of patient safety materials, as defined under Minnesota law, to the extent that releasing the same would waive any legal privilege applicable to said materials. This section shall survive the termination of this Agreement.

The Parties agree that no personal information, as defined by Minnesota State Statute §325E.61, shall be exchanged under this Agreement. If any Personal Information (as defined by §325E.61) is accidentally exchanged under this Agreement, the Parties agree to protect it in accordance with §325E.61 until such time as it can be returned or destroyed as determined by APPLE TREE. This section shall survive the termination of this Agreement.

1. **Promotional Materials.** Except as otherwise stated in this Agreement, each Party agrees not to use the name, trademark, service mark, or design registered to the other Party or its affiliates in any publicity, promotional, or advertising material, unless review and written approval of the intended use is obtained from the other Party prior to the release of any such material.
2. **Release of Information.** The provisions of this Agreement are confidential and protected from disclosure to a third party, other than its agents, attorneys, consultants and designees, unless disclosure is required by law, or said third party is bound to the same level of confidentiality set forth in this Agreement.
3. **Severability.** In the event any provision of this Agreement is rendered invalid or unenforceable by any court of competent jurisdiction, the remaining provisions of this Agreement shall remain in full force and effect. Further, the Parties shall work together in good faith to renegotiate and amend the Agreement to comply with the requirements of law. If the Parties fail to reach such an amendment satisfying each of the Parties within ninety (90) days' following a written request by one of the Parties, then either Party may terminate this Agreement upon thirty (30) days' written notice, without further obligation or penalty, financial or otherwise, to the other Party.
4. **Unforeseen Circumstances.** Neither of the Parties will be deemed in violation of this Agreement if prevented from performing any of its duties and responsibilities under this Agreement for circumstances beyond its reasonable control. In the event either Party is unable to perform its duties and responsibilities due to said circumstances for a period exceeding ninety (90) days, the other Party has the right to terminate this Agreement upon written notice to the affected Party.

**Exhibit D**

Business Associate Agreement

**SECTION 1. DEFINITIONS**

**EXHIBIT D**

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BAA”) is attached to and made part of that certain Research Collaboration Agreement between Institute and APPLE TREE dated [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_] (the “Agreement”). Any capitalized terms used herein and not defined shall have the meanings given to them in the Agreement. In addition, the following terms used in this BAA shall have the same meaning as those terms in the “HIPAA Rules” (as hereinafter defined): Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use. Capitalized terms used in the BAA are as defined in 45 CFR Parts 160, 162 and 164 (the "**Privacy Rule**" and the "**Security Rule**"). Additionally,

a. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103, and in reference to the Party to this BAA, shall mean Research Collaborator.  
b. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the Party to this BAA, shall mean APPLE TREE.

**SECTION 2. DUTIES AND RESPONSIBILITIES OF THE COVERED ENTITY**

2.1  Covered Entity agrees to comply with HIPAA Rules, including all notification requirements under the HITECH Act, and use its best efforts to limit access to the minimum amount of Protected Health Information, to the minimum number of personnel for the minimum of amount of time necessary for Business Associate to accomplish the intended purpose of such use, disclosure, or request, respectively.

2.2  Covered Entity shall make available to the Business Associate a copy of its Notice of Privacy Practices upon request, and notify Business Associate of any limitations in its Notice of Privacy Practices to the extent that such limitations affect Business Associate's Use or Disclosure of Protected Health Information.

2.3  Covered Entity shall notify Business Associate of any changes in or revocation of permission by an Individual regarding the Use or Disclosure of Protected Health Information, to the extent that such changes may affect Business Associate's Use or Disclosure of Protected Health Information.

2.4  Covered Entity agrees to not request that Business Associate Use or Disclose PHI in any manner that would not be permissible under HIPAA if done by Covered Entity.

**SECTION 3. DUTIES AND RESPONSIBILITIES OF THE BUSINESS ASSOCIATE**

* 1. Use/Disclosure.

1. Business Associate may only use the Protected Health Information received by Business Associate in its capacity to Covered Entity, if necessary: (A) for the proper management and administration of the Business Associate; or (B) to carry out the legal responsibilities of the Business Associate.
2. Business Associate agrees to not use or further disclose the Protected Health Information other than as expressly permitted or required by this BAA or as required by law.
3. Business Associate may disclose the Protected Health Information received by Business Associate in its capacity to Covered Entity, if: (A) the Disclosure is required by law; or (B) (1) Business Associate obtains reasonable assurances from the person to whom the Protected Health Information is disclosed that it will be held confidentially and Used or further Disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the person agrees to notify Business Associate of any instances of which it is aware in which the confidentiality of the Protected Health Information has been breached.
4. Except as required by law, Business Associate shall not de-identify the Protected Health Information for any purpose.
   1. Subcontractors.
   2. Business Associate agrees and shall advise its employees, subcontractors and agents that they may only use or further disclose Protected Health Information for the proper management and administration of Business Associate, in a manner that would not violate the requirements of 45 CFR Part 164.
   3. Business Associate shall require its agents, employees and subcontractors (as applicable) to immediately advise Business Associate of any and all Uses and Disclosures of Protected Health Information which are not expressly permitted under the BAA between Business Associate and Covered Entity.
   4. Business Associate shall ensure that any agents, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Business Associate on behalf of Covered Entity: (i) agree to the same restrictions and conditions that apply to Business Associate with respect to such Protected Health Information and (ii) unless, specifically agreed upon in writing by Covered Entity and Business Associate, are located in the United States.
   5. Business Associate shall ensure that any agent, including a subcontractor, to whom it Discloses Electronic Protected Health Information received from, or created or received by the Business Associate on behalf of Covered Entity, agrees to implement reasonable and appropriate Safeguards to protect such Electronic Protected Health Information that apply to Business Associate with respect to such Electronic Protected Health Information.
   6. Data Aggregation Services.
   7. Business Associate may Use or Disclose PHI to provide data aggregation services relating to the Health Care operations of Covered Entity. Such Use may only occur with prior express written approval of Covered Entity.
   8. Business Associate agrees to provide access, at the request of the Covered Entity, and in the time and manner required by the Covered Entity, to Protected Health Information 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 CFR Part 164.
   9. Business Associate agrees to make any amendment to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees pursuant to 45 CFR 164.526 at the request of a Covered Entity or an Individual immediately upon request by the Covered Entity.
5. 3.4  Safeguards.
6. Business Associate shall use appropriate safeguards to prevent Use or Disclosure of the information other than as provided for by this Agreement. Such safeguards shall include (but shall not be limited to) those safeguards provided by state and federal laws, rules and regulations.
7. Business Associate shall use its best efforts to ensure that Protected Health Information in the possession of Business Associate's employees is kept secure and inaccessible to non-employees.
8. Business Associate shall not store any Protected Health Information on any portable device without obtaining prior approval from Covered Entity's Information Security Office.
9. Business Associate shall not remove any Protected Health Information or any material containing Protected Health Information from Covered Entity's premises or computer system without the prior express written approval of Covered Entity.
10. Business Associate shall notify Covered Entity prior to any changes in Business Associate's methodology regarding the services provided under the Agreement.
11. Business Associate agrees to take all reasonable steps to cure a Breach or violation of this Agreement, including but not limited to those steps required by Covered Entity, when an employee, agent or subcontractor of Business Associate uses or discloses Protected Health Information in any way that is not permitted by this Agreement and/or 45 CFR Parts 160 and 164.
12. In order to ascertain compliance with this Business Associate Agreement, Business Associate agrees that Covered Entity may audit Business Associate's records relating to the Agreement between Business Associate and Covered Entity, with reasonable notice and at dates and times mutually agreed upon.
13. Business Associate agrees to meet with Covered Entity to discuss further safeguards and their implementation. Such meetings will occur at times, places and dates as mutually agreed upon by the Parties.
14. Business Associate agrees to implement any additional reasonable safeguards deemed necessary by Covered Entity on a timely basis.
15. Business Associate will add the following to any invoice template for invoices mailed as a result of the services provided under this Agreement: If you have received this letter in error, please notify the APPLE TREE Health System Privacy Officer immediately at 1- (570)-271-7360.
16. Business Associate shall implement appropriate Administrative, Physical, and Technical Safeguards (collectively the “Safeguards”) that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the Electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of the Covered Entity. Such Safeguards shall include (but shall not be limited to) those safeguards provided by state and federal laws, rules and regulations. Business Associate shall abide by those administrative, physical and technical safeguards enumerated in the Security Rule, as applicable.

3.5 Reporting.

A. Business Associate shall report to Covered Entity any Use or Disclosure of the Protected Health Information not provided for by this BAA of which Business Associate becomes aware, including breaches of unsecured Protected Health Information as required at 45 CFR 164.410, and any Security Incident of which it becomes aware. Any such breach or Security Incident shall be reported in writing by Business Associate to Covered Entity within forty-eight hours (48 hours) from the time that Business Associate becomes aware of such breach or Security Incident. Research Collaborator shall provide APPLE TREE with the following data, to the extent possible, of such use or disclosure, within ten (10) days after providing the initial breach or Security Incident report: (1) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known; (2) A description of the types of unsecured DATA that were involved in the Breach (such as full name, Social Security number, date of birth, home address, account number, or disability code); (3) The steps individuals should take to protect themselves from potential harm resulting from the Breach; (4) A brief description of what the Institute involved is doing to investigate the Breach, to mitigate losses, and to protect against any further Breaches; (5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web Institute, or postal address within such ten (10) day notification period. Institute further agrees that APPLE TREE shall prepare and send the Breach notification letter to Individuals affected by such Breach as appropriate. The Parties agree to cooperate with each other as may be necessary to resolve such matters. Research Collaborator shall require anyone to whom Institute discloses the DATA to abide by the same notification requirement.

B. Business Associate shall make available the Protected Health Information required to provide an accounting of Disclosures in accordance with 45 CFR 164.528. Such information shall be reported to Covered Entity by Business Associate within thirty (30) days.

C. Business Associate shall provide Covered Entity with written notice of any Breach involving Protected Health Information no later than ten (10) days after the discovery of such Breach. Business Associate shall provide Covered Entity with the following data, to the extent possible: (1) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known; (2) A description of the types of unsecured protected health information that were involved in the Breach (such as full name, Social Security number, date of birth, home address, account number, or disability code); (3) The steps individuals should take to protect themselves from potential harm resulting from the Breach; (4) A brief description of what the Business Associate involved is doing to investigate the Breach, to mitigate losses, and to protect against any further Breaches; (5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address within such ten- (10-) day notification period. Business Associate further agrees that Covered Entity shall prepare and send the Breach notification letter to Individuals affected by such Breach as appropriate.

3.6  Business Associate shall make any and all Protected Health Information available to Covered Entity in accordance with 45 CFR 164.524.

3.7  Business Associate shall make available Protected Health Information for amendment by Covered Entity and incorporate any amendments to Protected Health Information in accordance with 45 CFR 164.526.

3.8  Business Associate shall make its internal practices, books, and records directly relating to the Use and Disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary, Department of Health and Human Services or his designee ("Secretary"), for purposes of determining Covered Entity's compliance with applicable laws, rules and regulations.

3.9  Business Associate acknowledges that Section 13404 of the HITECH Act includes additional requirements applicable to Business Associates to secure Protected Health Information. Business Associate agrees to adhere to any and all additional privacy and security requirements described within the HITECH Act, as applicable.

3.10  Business Associate agrees to promptly mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this BAA.

3.11  Business Associate agrees to limit access to the minimum amount of Protected Health Information, to the minimum number of personnel for the minimum amount of time necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.

3.12  To the extent that Business Associate is required to carry out one or more of Covered Entity’s obligations under Subpart E of 45 CFR Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation.

3.13  Each Party agrees that other Party may suffer irreparable harm if the other Party were to breach, or threaten to breach, any provision of this BAA and that the such Party will by reason of such breach, or threatened breach, be entitled to seek injunctive relief in a court of appropriate jurisdiction, without the need to post any bond, and the other Party further consents and stipulates to the entry of such injunctive relief in such a court. This Section shall not, however, diminish the right of either Party to claim and recover damages and other appropriate relief but shall be in addition to any other rights and remedies available to such Party under this BAA, the Agreement, and at law and in equity.

**SECTION 4. GENERAL PROVISIONS**

4.1  A reference in this BAA to a section in the Privacy Rule, Security Rule, ARRA and/or HITECH means the section in effect or as amended.

4.2  The Parties hereto agree to take such action as is necessary to amend this BAA from time to time as is necessary for Covered Entity to comply with the requirements of HIPAA, including any amendments to the HITECH Act, as applicable.

4.3  The duties and responsibilities of the Parties under this BAA shall survive termination of this BAA.

4.4  Any ambiguity in this BAA shall be resolved to permit Covered Entity and/or Business Associate to comply with HIPAA.

4.5  All notices and communications related to this BAA must be in writing and will be deemed given: (i) when personally delivered, (ii) upon confirmation of a facsimile transmittal, or (iii) upon receipt when deposited with the United States Postal Service, postage prepaid, addressed as follows or to such other person, fax and/or address as the party to receive may designate by notice to the other:

Apple Tree Dental Corporate Office  
2442 Mounds View Blvd Mounds View, MN 55112

If to Business Associate:

Research Collaborator Contact Information

**SECTION 5. TERM/TERMINATION**

5.1  In addition to any termination provisions otherwise set forth in this BAA, upon either Party’s knowledge of a material breach by the other Party, such non-breaching Party shall:

* 1. Provide the breaching party at least thirty (30) days to cure the breach or end the violation and may terminate this BAA and the Agreement if the breaching Party does not cure the breach or end the violation within such period;
  2. Immediately terminate this BAA and the Agreement if the breaching Party has breached a material term of this BAA and cure is not possible;
  3. If neither termination nor cure is feasible, report the violation to the Secretary.

5.2  Upon termination of this BAA, Business Associate shall at Covered Entity's direction return and/or destroy all Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity that Business Associate still maintains in any form and retain no copies of such Protected Health Information or, if such return or destruction is not feasible, extend the protections of this BAA to the Protected Health Information and limit further Uses and Disclosures to those purposes that make the return or destruction of the Protected Health Information infeasible.

A. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon Covered Entity's confirmation that such return or destruction is infeasible, Business Associate shall extend the protections under this BAA and limit further Uses and Disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

**Exhibit E**

Budget

1. Budget Narrative
2. Staff/Personnel Table
3. Goods/Services Table
4. Payment Schedule
5. FTE Commitment of Research Collaborator Staff