

Business Associate Agreement

This Business Associate Agreement (“Agreement”), effective, April 5, 2003, (Effective Date”), is entered into by and between Medical Technology International, Ltd. (the “Contractor”) with an address at 11541 E. Winchester Lane, Ellicott City, Maryland 21042 and

Practice/Licensee: _____

Address: _____

WITNESSETH:

WHEREAS, the US department of Health and Human Services (“HHS”) has issued final regulations, pursuant to the Health Insurance Portability Accountability Act of 1996 (“”), governing the privacy of individually identifiable health information obtained, created or maintained by certain entities, including healthcare providers (the “Final Privacy Rule”), and meant to protect information regarding individuals treated by those providers. Throughout this Agreement, “Individual” shall have the same meaning as the term “individual” in 45 C.F.R. & 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. & 164.502(g); and

WHEREAS, the Final Privacy Rule requires that the Practice enter into this Agreement with Contractor in order to protect the privacy of individually identifiable health information (“Protected Health Information”, or “PHI”) maintained by the Practice as that term is defined in 45 C.F.R. & 164.501. The scope of this Agreement is limited to the information created or received by Contractor from or on behalf of the Practice; and

WHEREAS, Contractor and its employees, affiliates, agents or representatives may access paper and/or electronic records containing PHI in carrying out their obligations to the Practice pursuant to either an existing or contemporaneously executed agreement for services (“Services Agreement”); and

WHEREAS, the Parties desire to enter into this Agreement to protect PHI, and to amend any agreements between them, whether oral or written, with the execution of this Agreement;

NOW, THEREFORE for and in consideration of the premises and mutual covenants and agreements contained herein the parties agree as follows:

1. Services Agreements.

- .1 Existing Services Agreements. Practice and Contractor are parties to a Services License Agreement, which was executed prior to the Effective Date, currently in effect, and incorporated by reference. All existing Agreements between the Parties are incorporated into this Agreement. In the event of conflict between the

terms of any Services Agreement and this Agreement, the terms and conditions of the original License Agreement shall govern.

- .2 Use and Disclosure of PHI to Provide Services. MTI will not use or further disclose PHI (as such term is defined in the Final Privacy Rule) other than as permitted or required by the terms of the Service Agreement or as required by law. Except as otherwise provided in this document, the Contractor may make any and all uses of PHI necessary to perform its obligations under the applicable Services Agreement. All other uses not authorized by this Agreement are prohibited.

2. **Additional Contractor Activities.** Except as otherwise provided in this Agreement, the Contractor:

Agrees not to use or further disclose PHI other than as permitted or required by the Agreement or as required by law, as that phrase is defined at 45 CFR 164.501, provided that such use or disclosure would not violate the Final Privacy Rule if done by the Practice.

Represents to Practice that (i) any disclosures it makes will be permitted under applicable laws, and (ii) the Contractor will obtain reasonable written assurances from any person to whom the PHI will be disclosed only as required and permitted under the Final Privacy Rule and other applicable laws, that any such person agrees to be governed by the same restrictions and conditions contained in this Agreement, and that such person will notify the Contractor of any instances of which it is aware in which the confidentiality of the PHI has been breached.

May bring together the Practice's PHI in Contractor's possession with the PHI of other covered entities that the Contractor has in its possession through its capacity as a contractor to such other covered entities, provided that the purpose of bringing the PHI information together is to provide the Practice with the data analyses relating to its Healthcare Operations, as such term is defined in the Final Privacy Rule. The Contractor will not unintentionally disclose the PHI obtained from the Practice to another Practice without written authorization from Practice.

May de-identify any and all PHI provided that the de-identification confirms to the requirements of applicable law as provided for in C.F.R. & 164.154(b) and that Contractor maintains such documentation as required by applicable law, as provided for in 42 C.F.R. & 164.514(b). The Parties understand that the properly de-identified information is not PHI under the terms of this Agreement.

3. **Contractor Covenants.** Contractor agrees to:

Use or further disclose the minimum necessary PHI in performing the activities called for under the Service Agreement;

Not to use or further disclose PHI except as permitted under this Agreement, the Final Privacy Rule.

Use appropriate safeguards to prevent the use or disclosure of PHI other than as provided for in this Agreement;

Report to Practice any use or disclosure of the PHI not permitted by this Agreement.

In conjunction with the requirements of Section 2.2, ensure that any subcontractors or agents to whom it provides PHI received from, or created or received by the Contractor on behalf of the Practice, agree to the same restrictions and conditions that apply to the Contractor with the respect to the PHI;

Contractor agrees to document such disclosures of PHI and information related to such disclosures as would be required for the Practice to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. & 164.528. Within ten days of a request other than Treatment, Healthcare Operations or Payment, as such terms are defined in the Final Privacy Rule. The report to the Practice shall identify: (i) the subject of the PHI (i.e., patient name or identifier); (ii) the PHI disclosed; and (iii) the purpose of the disclosure in accordance with the accounting requirements of 45 C.F.R. & 164.528;

Maintain the integrity of any PHI transmitted by or received from Practice;

Comply with HIPAA policies and procedures with respect to the privacy and security of PHI and other Practice records, as well as policies and procedures with respect to access and use of Practice's equipment and facilities;

Except as otherwise limited in this Agreement, Contractor may use PHI to provide data aggregation services to the Practice as permitted by C.F.R. & 164.504(e)(2) (i)B).

4. Practice Covenants.

Practice shall provide Contractor with the notice of privacy practices that Practice procedures in accordance with 45 C.F.R. & 164.520, as well as any changes to such notice.

Practice shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose PHI, if such changes affect Contractor's permitted or required uses and disclosures.

Practice shall notify Contractor of any restriction to the use or disclosure of PHI that Practice has agreed to in accordance with 45 C.F.R. & 164.522.

Practice shall not request Contractor to use or disclose OHI in any manner that would not be permissible under the Privacy Rule if done by Practice. This provision specifically accepts those situations in which the Contractor will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of the Contractor.

5. Access to Books and Records Regarding PHI. Within ten (10) days of the notice by the Practice, the Contractor will make its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by the Contractor on behalf of, Practice available to the Secretary of the U.S. Department of Health and Human Services for purposes of determining Practice compliance with the Final Privacy Rule.

6. Disposition of PHI upon Termination. The Contractor will, at termination or expiration of the Services Agreement, if feasible, return or destroy all PHI received from, or created or received by the Contractor on behalf of, Practice which the Contractor and/or its subcontractors or agents still maintain in any form, and will not retain any copies of such information. Limit further uses and disclosures to those purposes that make the return or destruction of the PHI not feasible.

7. Representation and Warranties

Mutual Representation and Warranties of the Parties

Each Party represents and warrants to the other Party:

- (a) that it is duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized or licensed, it has the full power to enter into this Agreement and to perform its obligations described in this Agreement, and that the performance by it of its obligations under this Agreement have been duly authorized by all necessary corporate or other actions and that such performance will not violate any provision of any organizational charter or by laws.
- (b) That neither the execution of this Agreement, nor its performance, will directly or indirectly violate or interfere with the terms of another agreement to which it is a party, or give any governmental entity the right to suspend, terminate, or modify any of its governmental authorizations or assets required for its performance.

(c) That all of its employees, agents, representatives and members of its workforce, whose services maybe used to fulfill obligations under this Agreement are or shall be appropriately informed of the terms of this Agreement, and are under legal obligation to each Party, respectively, by contract or otherwise, sufficient to enable each Party to fully comply with all provisions of this Agreement.

(d) That it will reasonably cooperate with the other Party in the performance of the mutual obligations under this Agreement.

8.Term. Unless otherwise terminated as provided in Section 9, this Agreement shall become effective on the Effective Date and shall have a term run concurrently with that of the Services Agreement

9.Termination.

Generally. This Agreement will automatically terminate without any further action of the Parties upon the termination or expiration of the Services Agreement; provided, however, certain provisions and requirements of this Agreement shall survive such expiration or termination in accordance with Section 10.

10. Effect of Termination. Upon termination pursuant to Section 9, Contractor agrees to return or destroy all PHI pursuant to 45 C.F.R. & 164.504(e)(2)(1), if it is feasible to do so. Prior to doing so, the Contractor further agrees to recover any OHI in the possession of its subcontractors or agents.

11. Third Party Beneficiaries. Nothing in this Agreement shall be construed to create any third party beneficiary right in any person.

12. Amendments; Waiver. Both the Practice and the Contractor agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Practice to comply with the requirements of the Final Privacy Rule and HIPAA. This Agreement may not be modified, nor shall any provisions be waived or amended, except in a writing duly signed by authorized representatives of the Parties. The failure of either Party to enforce at anytime any provision of this Agreement shall not be construed to be a waiver of such provision, nor in any way to affect the validity of the Agreement or the right of either Party thereafter to enforce each and every such provision.

13. Notices. Any notice required or permitted under this Agreement shall be given in writing and delivered by hand, via a nationally recognized overnight delivery

services (e.g., Federal Express), or via registered mail or certified mail, postage pre-paid and return receipt requested, to the Practice.

Notice of a change in address of one of the parties shall be given in writing to the other party as provided above.

- 14. Regulatory Reference.** A reference in this Agreement to a section in the Final Privacy Rule means the section in effect or as amended, and for which compliance is required.
- 15. Survival.** The respected rights and obligations of Contractor under this Agreement shall survive termination of this Agreement, pursuant to the Software and License Agreement.
- 16. Interpretation.** Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits the Practice to comply with the Privacy Rule and which protects the privacy of the Individual.

INTENDING TO BE LEGALLY BOUND, the Parties hereto have duly executed this Agreement as of the Effective Date:

Practice:

DATE

Contractor:

DATE

