

PenRad

...the mammography information specialists...keeping you in touch...

HIPAA Business Associate Agreement

This Business Associate Agreement is entered into by and between _____, ("Covered Entity") on behalf of itself, and its current and future subsidiaries and affiliates, and PenRad Technologies, Inc., ("Business Associate") including all current and future lines of business, affiliates, and subsidiaries. Covered Entity and Business Associate may have entered into various arrangements, and may in the future enter into additional arrangements (collectively, the "Contracts") pursuant to which Business Associate provides various items or services to Covered Entity or for its patients. This Agreement modifies and supplements the terms and conditions of the Contracts, and the provisions set forth herein shall be deemed a part of the Contracts.

1.0 DEFINITIONS

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

- 1.1 Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- 1.2 Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.
- 1.3 Protected Health Information. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR § 164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- 1.4 Required By Law. "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR § 164.501.
- 1.5 Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

2.0 OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

- 2.1 Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this Agreement or as required by law.
- 2.2 Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- 2.3 Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- 2.4 Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
- 2.5 Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

- 2.6 Business Associate agrees to make internal practices, books, and records, including policies and procedures and Protected Health Information, 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 Covered Entity, or to the Secretary, in a timely manner or designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- 2.7 Business Associate agrees to document such 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 CFR § 164.528.
- 2.8 Business Associate agrees to provide to Covered Entity or an Individual, in a timely manner, information collected in accordance with Section 2.7 of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.
- 3.0 PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE
- 3.1 Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the PenRad Mammography System Partner License Agreement, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of the Covered Entity.
- 4.0 SPECIFIC USE AND DISCLOSURE PROVISIONS
- 4.1 Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Covered Entity or to carry out the legal responsibilities of the Business Associate.
- 4.2 Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- 4.3 Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR §164.504.
- 4.4 Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502.
- 5.0 OBLIGATIONS OF COVERED ENTITY
- 5.1 Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.
- 5.2 Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.
- 5.3 Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

6.0 PERMISSIBLE REQUESTS BY COVERED ENTITY

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

7.0 TERM AND TERMINATION

7.1 Term. The Term of this Agreement shall become effective from the date specified in the PenRad Mammography System Partner License Agreement, and remain in effect for as long as that document is enforceable. It shall terminate when all of the Protected Health Information 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 Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

7.2 Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business

Associate, Covered Entity shall either:

- a. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or
- b. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
- c. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

8.0 EFFECT OF TERMINATION

8.1 Except as provided in paragraph 2 of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

8.2 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 determination that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information 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.

9.0 MISCELLANEOUS

9.1 Regulatory References. Any reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

9.2 Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

9.3 Survival. The respective rights and obligations of Business Associate under Section 8.0 of this Agreement shall survive the termination of this Agreement.

9.4 Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

If the foregoing meets with your understanding and approval, please show your acceptance and agreement by signing and returning one copy of this Agreement to the undersigned, at which point this Agreement shall become effective as of the date indicated below. By signing below, the undersigned warrants that he/she is an authorized agent of Covered Entity, and his/her signature is binding upon Covered Entity.

ACCEPTED AND AGREED TO:

Covered Entity:

Business Associate:

PenRad Technologies, Inc.

By: _____

Print Name: _____

Title: _____

Date: _____

By: _____

Print Name: _____

Title: _____

Date: _____