HIPAA BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement") is entered into effective as of the date that the last party executes this Agreement, by and between Lake County, Florida, a political subdivision of the State of Florida, by and through its Board of County Commissioners (collectively referred to as "Covered Entity"), and [Vendor Name] a [Entity Type], its successors and assigns ("Business Associate"), (each a "Party" and collectively, the "Parties"), in order to comply with the Privacy Rule, Security Rule and HITECH Act, as defined below. The Parties mutually agree as follows:

Section 1. Definitions.

Terms used, but not otherwise defined in this Agreement, will have the same meaning as those terms in the Privacy Rule, Security Rule, and HITECH Act.

a. **Agent.** "Agent" will have the meaning as determined in accordance with the federal common law of agency.

b. **Breach.** "Breach" will have the same meaning as the term "breach" in 45 CFR §164.402.

c. **Data Aggregation.** "Data Aggregation" will have the same meaning as the term "data aggregation" in 45 CFR §164.501.

d. **Designated Record Set.** "Designated Record Set" will have the same meaning as the term "designated record set" in 45 CFR §164.501.

e. **Disclosure.** "Disclosure" and "Disclose" will have the same meaning as the term "Disclosure" in 45 CFR §160.103.

f. **Electronic Health Record.** "Electronic Health Record" will have the same meaning as the term in Section 13400 of the HITECH Act**.**

g. **Health Care Operations.** "Health Care Operations" will have the same meaning as the term "health care operations" in 45 CFR §164.501.

h. **HIPAA Rules.** "HIPAA Rules" will mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

i. **HITECH Act**. "HITECH Act" will mean The Health Information Technology for Economic and Clinical Health Act, part of the American Recovery and Reinvestment Act of 2009 ("ARRA" or "Stimulus Package"), specifically DIVISION A: TITLE XIII Subtitle D—Privacy, and its corresponding regulations as enacted under the authority of the Act.

j. **Individual**. "Individual" will have the same meaning as the term "individual" in 45 CFR §160.103 and will include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).

k. **Minimum Necessary**. "Minimum Necessary" will mean the Privacy Rule Standards found at 45 CFR §164.502(b) and 45 CFR §164.514(d)(1).

l. **Privacy Rule**. "Privacy Rule" will mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

m. **PHI**. "PHI" will have the same meaning as the term "protected health information" in 45 CFR §160.103, limited to the information created, received, maintained or transmitted by Business Associate on behalf of Covered Entity.

n. **Required By Law**. "Required By Law" will have the same meaning as the term "required by law" in 45 CFR §164.103.

o. **Secretary**. "Secretary" will mean the Secretary of the Department of Health and Human Services or his or her designee.

p. **Security Incident**. "Security Incident" will have the same meaning as the term "Security Incident" in in 45 CFR §164.304.

q. **Security Rule**. "Security Rule" will mean the Standards for Security of Electronic Protected Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and C.

r. **Subcontractor**. "Subcontractor" will mean a person or entity "that creates, receives, maintains, or transmits protected health information on behalf of a business associate" and who is now considered a business associate, as the latter term is defined in in in 45 CFR §160.103.

s. **Subject Matter.** "Subject Matter" will mean compliance with the HIPAA Rules and with the HITECH Act.

t. **Unsecured Protected Health Information.** "Unsecured Protected Health Information" will have the same meaning as the term "unsecured protected health information" in 45 CFR §164.402.

u. **Use.** "Use" will have the same meaning as the term "Use" in 45 CFR §164.103.

Section 2. Obligations and Activities of Business Associate.

a. Business Associate agrees to not Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.

b. Business Associate agrees to use appropriate safeguards to prevent the Use or Disclosure of PHI other than as provided for by this Agreement. Business Associate further agrees to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any electronic PHI, as provided for in the Security Rule and as mandated by Section 13401 of the HITECH Act.

c. Business Associate agrees to 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 this Agreement. Business Associate further agrees to report to Covered Entity any Use or Disclosure of PHI not provided for by this Agreement of which it becomes aware, and in a manner as prescribed in this Agreement.

d. Business Associate agrees to report to Covered Entity any Security Incident, including all data Breaches or compromises, whether internal or external, related to PHI, whether the PHI is secured or unsecured, of which Business Associate becomes aware.

e. If the Breach, as discussed in paragraph 2(d), pertains to Unsecured PHI, then Business Associate agrees to report any such data Breach to Covered Entity within ten (10) business days of discovery of the Breach; all other compromises, or attempted compromises, of PHI must be reported to Covered Entity within twenty (20) business days of discovery. Business Associate further agrees, consistent with Section 13402 of the HITECH Act, to provide Covered Entity with information necessary for Covered Entity to meet the requirements of the HITECH Act, and in a manner and format to be specified by Covered Entity.

f. If Business Associate is an Agent of Covered Entity, then Business Associate agrees that any Breach of Unsecured PHI will be reported to Covered Entity ***immediately*** after the Business Associate becomes aware of the Breach, and under no circumstances later than one (1) business day after the Breach. Business Associate further agrees that any compromise, or attempted compromise, of PHI, other than a Breach of Unsecured PHI as specified in 2(e) of this Agreement, must be reported to Covered Entity within ten (10) business days of discovering the compromise, or attempted compromise.

g. Business Associate agrees to ensure that any Subcontractor, to whom Business Associate provides PHI, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information. Business Associate further agrees that restrictions and conditions analogous to those contained in this Agreement will be imposed on the Subcontractors via a written agreement that complies with all the requirements specified in

§164.504(e)(2), and that Business Associate may only provide the Subcontractors PHI consistent with Section 13405(b) of the HITECH Act. Further, Business Associate agrees to provide copies of the written agreements to Covered Entity within ten (10) business days of a Covered Entity's request for the written agreements.

h. Business Associate agrees to provide access, at the request of Covered Entity and during normal business hours, to PHI in a Designated Record Set to Covered Entity or, as directed by Covered Entity, to an Individual, in order to meet Covered Entity's requirements under 45 CFR §164.524, provided that Covered Entity delivers to Business Associate a written notice at least three (3) business days in advance of requesting such access. Business Associate further agrees, in the case where Business Associate controls access to PHI in an Electronic Health Record, or controls access to PHI stored electronically in any format, to provide similar access in order for Covered Entity to meet its requirements under the HIPAA Rules and under Section 13405(c) of the HITECH Act. These provisions do not apply if Business Associate and its employees or Subcontractors have no PHI in a Designated Record Set of Covered Entity.

i. Business Associate agrees to make any amendments to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 CFR §164.526, at the request of Covered Entity or an Individual. This provision does not apply if Business Associate and its employees or Subcontractors have no PHI from a Designated Record Set of Covered Entity.

j. Unless otherwise protected or prohibited from discovery or disclosure by law, Business Associate agrees to make internal practices, books, and records, including policies and procedures (collectively "Compliance Information"), relating to the Use or Disclosure of PHI and the protection of PHI, available to the Covered Entity or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the HIPAA Rules and the HITECH Act. Business Associate further agrees, at the request of Covered Entity, to provide Covered Entity with demonstrable evidence that its Compliance Information ensures Business Associate's compliance with this Agreement over time. Business Associate will have a reasonable time within which to comply with requests for such access or demonstrable evidence, consistent with this Agreement. In no case may access, or demonstrable evidence, be required in less than five (5) business days after Business Associate's receipt of such request, unless otherwise designated by the Secretary.

k. Business Associate agrees to maintain necessary and sufficient documentation of Disclosures of PHI as would be required for Covered Entity to respond to a request by an Individual for an accounting of such Disclosures, in accordance with 45 CFR §164.528.

l. On request of Covered Entity, Business Associate agrees to provide to Covered Entity documentation made in accordance with this Agreement to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. §164.528. Business Associate shall provide the documentation in a manner and format to be specified by Covered Entity. Business Associate will have a reasonable time within which to

comply with such a request from Covered Entity and in no case may Business Associate be required to provide such documentation in less than three (3) business days after Business Associate's receipt of such request.

m. Except as provided for in this Agreement, in the event Business Associate receives an access, amendment, accounting of disclosure, or other similar request directly from an Individual, Business Associate shall redirect the Individual to the Covered Entity.

n. To the extent that Business Associate carries out one or more of Covered Entity's obligations under the HIPAA Rules, the Business Associate must comply with all requirements of the HIPAA Rules that would be applicable to the Covered Entity.

o. Business Associate must honor all restrictions consistent with 45 C.F.R. §164.522 that the Covered Entity or the Individual makes the Business Associate aware of, including the Individual's right to restrict certain disclosures of PHI to a health plan where the individual pays out of pocket in full for the healthcare item or service, in accordance with Section 13405(a) of the HITECH Act.

Section 3. Permitted Uses and Disclosures by Business Associate.

a. Except as otherwise limited by this Agreement, Business Associate may make any Uses and Disclosures of PHI necessary to perform its services to Covered Entity and otherwise meet its obligations under this Agreement, if such Use or Disclosure would not violate the Privacy Rule, or the privacy provisions of the HITECH Act, if done by Covered Entity. All other Uses or Disclosures by Business Associate not authorized by this Agreement, or by specific instruction of Covered Entity, are prohibited.

b. Except as otherwise limited in this Agreement, Business Associate may Use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

c. Except as otherwise limited in this Agreement, Business Associate may Disclose PHI 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.

d. Except as otherwise limited in this Agreement, Business Associate may Use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 CFR §164.504(e)(2)(i)(B). Business Associate agrees that such Data Aggregation services will be

provided to Covered Entity only when such Data Aggregation services pertain to Health Care Operations. Business Associate further agrees that such services will not be provided in a manner that would result in Disclosure of PHI to another covered entity who was not the originator or lawful possessor of such PHI. Further, Business Associate agrees that any such wrongful Disclosure of PHI is a direct violation of this Agreement and must be reported to Covered Entity ***immediately*** after the Business Associate becomes aware of such Disclosure and, under no circumstances, later than three (3) business days after the Disclosure.

e. Business Associate may Use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR §164.502(j)(1).

f. Business Associate will make Uses, Disclosures, and requests for PHI consistent with the Minimum Necessary principle as Required by Law.

Section 4. Obligations and Activities of Covered Entity.

a. Covered Entity shall notify Business Associate of the provisions and any limitations in its notice of privacy practices of Covered Entity in accordance with 45 CFR §164.520, to the extent that such provisions and limitations may affect Business Associate's Use or Disclosure of PHI.

b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that the changes or revocation may affect Business Associate's use or disclosure of PHI.

c. Covered Entity shall notify Business Associate of any restriction to the Use or Disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR §164.522, and also notify Business Associate regarding restrictions that must be honored under section 13405(a) of the HITECH Act, to the extent that such restrictions may affect Business Associate's Use or Disclosure of PHI.

d. Covered Entity shall notify Business Associate of any modifications to accounting disclosures of PHI under 45 CFR §164.528, made applicable under Section 13405(c) of the HITECH Act, to the extent that such restrictions may affect Business Associate's Use or Disclosure of PHI.

e. Covered Entity shall not require Business Associate to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Rules if done by the Covered Entity.

Section 5. Term and Termination.

a. Term. Any and all previous business associate agreements entered into by the parties will be terminated on the same date this Agreement is executed. The term of this Agreement will take effect on the date that the last party executes this Agreement and will continue in effect unless

either party terminates this Agreement or the underlying services agreement entered into by the parties is terminated.

b. Termination for Cause by Covered Entity. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall give Business Associate written notice of such breach and provide reasonable opportunity for Business Associate to cure the breach or end the violation. Covered Entity may terminate this Agreement, and Business Associate agrees to such termination, if Business Associate has breached a material term of this Agreement and does not cure the breach or cure is not possible.

c. Termination for Cause by Business Associate. Upon Business Associate's knowledge of a material breach of this Agreement by Covered Entity, Business Associate shall give Covered Entity written notice of such breach and provide reasonable opportunity for Covered Entity to cure the breach or end the violation. Business Associate may terminate this Agreement, and Covered Entity agrees to such termination, if Covered Entity has breached a material term of this Agreement and does not cure the breach or cure is not possible.

d. Effect of Termination.

1. Except as provided in paragraph (2) of this section, upon termination of this Agreement for any reason, Business Associate shall **return all** PHI received from, or created or received by Business Associate on behalf of Covered Entity. This provision will also apply to PHI that is in the possession of Subcontractors of Business Associate. Business Associate shall not retain any copies of the PHI.

In the event that Business Associate determines that returning the PHI is infeasible, Business Associate shall provide to Covered Entity, within ten (10) business days, notification of the conditions that make return infeasible. Upon such determination, Business Associate shall extend the protections of this Agreement to such PHI and limit further Uses and Disclosures of such PHI to those purposes that make the return infeasible, for so long as Business Associate maintains such PHI.

Section 6. Indemnification

Business Associate will indemnify and hold harmless Covered Entity and any Covered Entity affiliate, officer, director, employee or agent in accordance with and to the fullest extent permitted by applicable law, including from and against any claim, cause of action, liability, damage, cost, or expense, including attorney's fees and court or proceeding costs, arising out of or in connection with any Breach by the Business Associate or any of its subcontractors or persons under Business Associate's control, or any violation of this Agreement by Business Associate or any of its subcontractors or persons under Business Associate's control.

Section 7. Miscellaneous

a. Regulatory References. A reference in this Agreement to a section in the Privacy Rule, Security Rule, or HITECH Act means the section as in effect or as amended from time to time.

b. Amendment. This Agreement may be modified only by a signed written agreement between Covered Entity and Business Associate. Further, the Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity and Business Associate to comply with the requirements of the Privacy Rule, Security Rule, the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), and the HITECH Act, and its corresponding regulations.

c. Survival. All representations, covenants, and agreements in or under this Agreement or any other documents executed in connection with the transactions contemplated by this Agreement, will survive the execution, delivery, and performance of this Agreement and such other documents. The respective rights and obligations of Business Associate under Section 5(d) of this Agreement will survive the termination or expiration of this Agreement.

d. Interpretation. Any ambiguity in this Agreement will be resolved to permit Covered Entity and Business Associate to comply with the Privacy Rule, Security Rule, the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), and the HITECH Act, and its corresponding regulations.

e. Severability. If any provision or provisions of this Agreement are determined by a court of competent jurisdiction to be unlawful, void, or unenforceable, this Agreement will not be unlawful, void or unenforceable, but will continue in effect and be enforced as though such provision or provisions were omitted.

f. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one original Agreement. Facsimile or electronically authenticated signatures will be accepted and enforceable in lieu of original signatures.

g. Entire Agreement. This Agreement supersedes all other prior and contemporaneous written and oral agreements and understandings between Covered Entity and Business Associate regarding this Subject Matter. It contains the entire Agreement between the parties. All other agreements entered into between Covered Entity and Business Associate, not related to this Subject Matter, remain in full force and effect.

h. Governing Law. This Agreement and the rights of the parties will be governed by and construed in accordance with Federal law as it pertains to the Subject Matter and will be governed by and construed in accordance with the laws of the State of Florida as it pertains to

contract formation and interpretation, without giving effect to its conflict of laws. Venue will lie in Lake County, Florida.

IN WITNESS WHEREOF, Business Associate and Covered Entity execute this Agreement on the respective dates under each signature.

BUSINESS ASSOCIATE

[VENDOR NAME]

_____

[Vendor's Authorized Representative, Title]

This _____ day of _____, 20___.

COVERED ENTITY

LAKE COUNTY, FLORIDA, through its
BOARD OF COUNTY COMMISSIONERS

_____
Leslie Campione, Chairman

This _____ day of _____, 20___.

ATTEST:

_____
Gary Cooney, Clerk
Board of County Commissioners
of Lake County, Florida

Approved as to form and legality:

_____
Melanie Marsh
County Attorney