



New Account Setup Form

Facility Information		Network Name:
Facility Name:		
Physician(s) Name		NPI #:
Shipping Contact:		
Shipping Address:		
City:	State:	Zip:
Phone:	Fax:	
Email:		

Shipping Terms		
Charged to Facility		\$65 standard overnight, \$75 priority overnight, \$150 first overnight.
Ship on Facility FedEx account		Facility FedEx Acct #:

Inventory Status		
Outright Purchase		

Billing Information		
Billing (Accounts Payable) Contact:		
Billing Address:		
City:	State:	Zip:
Phone:	Fax:	
Email:		

Sales Information	
Sales Representative:	Phone:

Please email completed form to orders@biowerxmedical.com

EXHIBIT B

Business Associate Agreement

This Agreement ("Agreement") is made and entered into this _____ of _____, _____ by _____ ("Business Associate"), whose business address is _____ and between BioWerX, LLC, ("Covered Entity"), whose business address 1496 SW 1st Way Deerfield Beach, FL 33441. Covered Entity and Business Associate are collectively referred to as the "Parties."

WHEREAS, Covered Entity is in the business of providing medical products/services; and

WHEREAS, Covered Entity wishes to engage, or has engaged, Business Associate to provide laboratory services or other medical products/services (the "Services");

WHEREAS, in order to provide the Services, Business Associate requires access to Covered Entity's Protected Health Information and the Parties wish to enter into this Agreement to ensure such Protected Health Information is maintained in a confidential manner.

NOW, THEREFORE, in consideration of the premises and mutual promises herein contained, it is agreed as follows:

1. **Definitions.** Terms used, but not otherwise defined in this Agreement, shall have the same meaning as those terms in the Privacy Rule, Security Rule, and HITECH Act.
 - a. **Agent.** "Agent" shall have the meaning as determined in accordance with the federal common law of agency.
 - b. **Breach.** "Breach" shall have the same meaning as the term "breach" in 45 CFR §164.402.
 - c. **Business Associate.** "Business Associate" shall mean _____.
 - d. **Covered Entity.** "Covered Entity" shall mean BioWerX, LLC.
 - e. **Data Aggregation.** "Data Aggregation" shall have the same meaning as the term "data aggregation" in 45 CFR §164.501.
 - f. **Designated Record Set.** "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR §164.501.
 - g. **Electronic Health Record.** "Electronic Health Record" shall have the same meaning as the term in Section 13400 of the HITECH Act.
 - h. **Federal Law.** "Federal Law" shall mean HIPAA, the HITECH Act and any regulations or guidance promulgated pursuant thereto, including, but not limited to the Privacy Rule and the Security Rule.

- i. Health Care Operations. “Health Care Operations” shall have the same meaning as the term “health care operations” in 45 CFR §164.501.
- j. HIPAA. “HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996.
- k. HITECH Act. “HITECH Act” shall 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.
- l. Individual. “Individual” shall have the same meaning as the term “individual” in 45 CFR §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
- m. 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.
- n. Protected Health Information. “Protected Health Information” shall 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.
- o. Required By Law. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR §164.103 and all provisions of disclosure and re-disclosure of patient records referenced in 42 C.F.R Part 2
- p. Secretary. “Secretary” shall mean the Secretary of the Department of Health and Human Services or his or her designee.
- q. Security Rule. “Security Rule” shall mean the Standards for Security of Electronic Protected Health Information at 45 C.F.R. parts §160 and §164, Subparts A and C.
- r. State Law. “State Law” shall mean Florida laws governing the confidentiality and privacy of medical records and protected information including, but not limited to, Chapters 181 and 182 of the Florida Health & Safety Code as amended by HB 300 (82nd Legislature) and any related regulations.
- s. Subject Matter. “Subject Matter” shall mean those topics addressed under Federal and State Law as those terms are defined herein..
- t. Underlying Agreement. “Underlying Agreement” shall mean the agreement entered into by the Parties pursuant to which the Business Associate provides Services to the Covered Entity.
- u. Unsecured Protected Health Information. “Unsecured Protected Health Information” shall have the same meaning as the term “unsecured protected health information” in 45 CFR §164.402.

2. Obligations and Activities of Business Associate.

- a. 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.
- b. Business Associate agrees that in receiving, storing, processing or otherwise dealing with any information from the Covered Entity about patients, it is fully bound by HIPAA and 42 C. F. R. Part 2.
- c. Business Associate agrees to resist in judicial proceedings if necessary, any efforts to obtain access to information pertaining to patients except as permitted by 42 C.F.R. Part 2.
- d. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of Protected Health Information 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 Protected Health Information, as provided for in the Security Rule and as mandated by Section 13401 of the HITECH Act.
- e. 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. Business Associate further agrees to report to Covered Entity any use or disclosure of Protected Health Information not provided for by this Agreement of which it becomes aware, and in a manner as prescribed herein.
- f. Business Associate agrees to report to Covered Entity any security incident, including all data Breaches or compromises, whether internal or external, related to Protected Health Information, whether the Protected Health Information is secured or unsecured, of which Business Associate becomes aware.
- g. If the Breach or disclosure, as discussed in paragraph 2(d) and (e), pertains to Unsecured Protected Health Information, then Business Associate agrees to verbally report any such data Breach or disclosure to Covered Entity within two (2) business days, followed by a written report within ten (10) business days of discovery of said Breach or disclosure; all other compromises, or attempted compromises, of Protected Health Information shall be reported to Covered Entity with 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 said section, and in a manner and format to be specified by Covered Entity. Written reports shall be supplemented as additional investigation is completed and additional information about the event is obtained by Business Associate. All reports shall contain at a minimum the information necessary for Covered Entity to provide any notice required by law, the steps the Business Associate took to mitigate any risk of harm to the persons whose information was disclosed or Breached and any steps taken, or that will be taken, to prevent similar events from occurring in the future.
- h. The Parties agree that the Business Associate is not an Agent of the Covered Entity.
- i. Business Associate agrees to ensure that any Agent, including a subcontractor, to whom Business Associate provides Protected Health Information, 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 herein shall be imposed on said Agents and/or subcontractors via a written agreement, and that Business Associate shall only provide said Agents and/or subcontractors Protected Health Information consistent with Section 13405(b) of the

HITECH Act. Further, Business Associate agrees to provide copies of said written agreements to Covered Entity within ten (10) business days of a Covered Entity's request for same.

- j. Business Associate agrees to provide access, at the request of Covered Entity and during normal business hours, 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 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 Protected Health Information in an Electronic Health Record, to provide similar access in order for Covered Entity to meet its requirements under Section 13405(c) of the HITECH Act and State Law. These provisions do not apply if Business Associate and its employees, subcontractors and Agents have no Protected Health Information in a Designated Record Set of Covered Entity.
- k. Business Associate agrees to make any amendment(s) to Protected Health Information 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, subcontractors and Agents have no Protected Health Information from a Designated Record Set of Covered Entity.
- l. 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 Protected Health Information, available to the Covered Entity or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule, Security Rule, 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 shall have a reasonable time within which to comply with requests for such access and/or demonstrable evidence. In no case shall 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.
- m. Business Associate agrees to maintain necessary and sufficient documentation of disclosures of Protected Health Information 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.
- n. 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 Protected Health Information in accordance with 45 C.F.R. §164.528. Business Associate shall provide said documentation in a manner and format to be specified by Covered Entity. Business Associate shall have a reasonable time within which to comply with such a request from Covered Entity and in no case shall Business Associate be required to provide such documentation in less than three (3) business days after Business Associate's receipt of such request.
- o. 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 promptly redirect the Individual to the Covered Entity and provide Covered Entity notice of such request within five (5) business days of receipt.

3. Permitted Uses and Disclosures by Business Associate.

- a. Acknowledges that in receiving, transmitting, transporting, storing, processing or otherwise dealing with any information received from the Covered Entity (Protected Health Information), it is fully bound by the provisions of Federal Law and State Law regarding same and may not use or disclose the information except as permitted or required by this Agreement or by law.
- b. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information 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 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.
- d. 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 45 CFR §164.504(e)(2)(i) (B). Business Associate agrees that such Data Aggregation services shall be provided to Covered Entity only wherein said services pertain to Health Care Operations of Covered Entity. Business Associate further agrees that said services shall not be provided in a manner that would result in disclosure of Protected Health Information to another covered entity who was not the originator and/or lawful possessor of said Protected Health Information. Further, Business Associate agrees that any such wrongful disclosure of Protected Health Information is a direct violation of this Agreement and shall be reported to Covered Entity *immediately* after the Business Associate becomes aware of said disclosure and, under no circumstances, later than three (3) business days thereafter.
- e. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with §164.502(j)(1).

4. Obligations and Activities of Covered Entity.

- a. Covered Entity shall notify Business Associate of the provisions and any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR §164.520, to the extent that such provisions and limitation(s) may affect Business Associate's use or disclosure of Protected Health Information.
- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that the changes or revocation may affect Business Associate's use or disclosure of Protected Health Information.
- c. 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, 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 Protected Health Information.

- d. Covered Entity shall notify Business Associate of any modifications to accounting disclosures of Protected Health Information 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 Protected Health Information.
- e. Covered Entity agrees not to request anything of Business Associate which would cause Business Associate to violate the HITECH Act or any other law or regulation. Covered Entity agrees to indemnify and hold harmless Business Associate from and against any claims against Business Associate which result from Business Associate's acts which were requested by Covered Entity.

5. **Term and Termination.**

- a. **Term.** The Term of this Agreement shall be effective as of Effective Date and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate, its employees, agents and contractors 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 Agreement.
- 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 within a reasonable amount of time given the nature of the breach but not to exceed thirty (30) days, or the breach is of such nature that cure is not possible. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary. In the event this Agreement is Terminated for Cause under this section 5(b), such termination shall be cause for termination of the Underlying Agreement without penalty for early termination of the Underlying Agreement.
- 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. If neither termination nor cure is feasible, Business Associate shall report the violation to the Secretary. Additionally, Business Associate agrees, to conduct in normal business relations, any and all dealings with BioWerX, LLC and any and all outside clients/vendors in a honest, forthright, and ethical manner. If such Business Associate displays such conduct that is deemed to violate the forementioned, termination of such relationship as a Business Associate including any additional contracts with Business Associate may result in immediate termination of the relationship, including but not limited to, any additional contracts/agreements with Business Associate. Such determination will be made by principles of BioWerX, LLC.

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 or destroy all Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity. This provision shall also 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.
2. In the event that Business Associate reasonably determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity, within ten (10) business days, notification of the conditions that make return or destruction infeasible. Upon such determination, 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.

6. Entire Agreement.

- a. 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.
- b. This Agreement may be modified only by a signed written agreement between Covered Entity and Business Associate.
- c. All other agreements entered into between Covered Entity and Business Associate, not related to this Subject Matter; remain in full force and effect.

7. Governing Law

- a. Except where State Law imposes more restrictive requirements of the Parties, this agreement and the rights of the parties shall be governed by and construed in accordance with Federal law as it pertains to the Subject Matter and shall 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 any effect to its conflict of laws. The parties agree that any appropriate state court sitting in Dallas County, Florida, or any Federal Court sitting in Dallas, Florida, Northern District of Florida shall have exclusive jurisdiction of any case or controversy arising under or in connection with this Agreement and shall be a proper forum in which to adjudicate such case or controversy.
- b. Each party irrevocably consents to the jurisdiction of such courts and irrevocably waives, to the fullest extent permitted by law, the defense of an inconvenient forum to the maintenance of such suit, action or proceeding in any such court and further waives the *right to object, with respect to such suit, action or proceeding that such court does not have jurisdiction over such party.*

8. Miscellaneous.

- a. Regulatory References. A reference in this Agreement to a section in the Privacy Rule, Security Rule, HITECH Act, or Federal Law or State Law means the section as in effect or as amended.
- b. 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 Federal Law and State Law.

- c. Survival. The respective rights and obligations of Business Associate under Section 5(d) of this Agreement shall survive the termination of this Agreement.
- d. Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Federal Law and State Law.
- e. Severability. If any provision or provisions of this Agreement is/are determined by a court of competent jurisdiction to be unlawful, void, or unenforceable, this Agreement shall not be unlawful, void or unenforceable thereby, but shall continue in effect and be enforced as though such provision or provisions were omitted.
- f. Indemnification. Business Associate shall indemnify and hold harmless Covered Entity from and against any and all claims, losses, liabilities, and costs related to the cost of notification and identity theft protection, associated with a Breach or unauthorized disclosure of PHI resulting from, or relating to, the acts or omissions of Business Associate, its employee, agents and subcontractors in connection with this Agreement.

9. **Counterparts.**

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

BioWerX, LLC (Covered Entity)

BY: _____

(Its Duly Authorized Officer)

Name: _____

Title: _____

And

_____ (Business Associate)

BY: _____

(Its Duly Authorized Representative)

Name: _____

Title: _____