# BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the “BAA”) is entered into between XXX and the individual or entity designated below whose signature is submitted as evidence of agreement to these the terms hereinafter referred to as “Covered Entity.” This BAA and any agreement for accreditation, certification or recognition entered into by Covered Entity and XXX establish the terms of the relationship between XXX and Covered Entity. The parties will comply with all ap plicable Federal and State Laws.

**WHEREAS**, Covered Entity desires to input data into data collection tools stored and maintained by XXXfor purposes of Covered Entity’s participation in patient care and which data may include certain Protected Health Information (as defined in 45 C.F.R. Section 160.103) that is subject to protection under the federal privacy regulations (the “Privacy Regulations”) and the federal security regulations (the “Security Regulations”) established at 45 C.F.R. Parts 160 and 164, as amended from time to time, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, Pub. Law No. 111-5 and its implementing regulations (“ARRA”), and this BAA shall apply to that PHI;

**WHEREAS**, Covered entity may have entered into, may subsequently enter into, or may enter into simultaneously with this BAA, an agreement with XXX in the form of a Collaborative Care Agreement (CCA), and this BAA shall be applicable to any such Contract entered into by Covered Entity and XXX, and XXX acts as a Business Associate of Covered Entity, as defined under the Privacy and Security Regulations;

**WHEREAS**, the Purpose of this BAA is to satisfy certain standards and requirements of the Privacy and Security Regulations, 45 C.F.R. Parts 160 and 164, and ARRA, as the same may be amended from time to time.

In consideration of the mutual promises below, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

# GENERAL PROVISIONS

Section 1. **Definitions.** Unless otherwise specified in the Contract or this BAA, all capitalized terms used herein and not otherwise defined shall have the meanings established by 45 C.F.R. Parts 160 and 164, and/or ARRA, as amended from time to time. “PHI” shall mean Protected Health Information, as defined in 45 C.F.R. Section 160.103, limited to the information received from or created or received on behalf of Covered Entity. “Electronic PHI” shall mean Electronic Protected Health Information, as defined in 45 C.F.R. Section 160.103,

limited to the information received from or created or received on behalf of Covered Entity. References in the Contract or this BAA to a section or subsection of title 42 of the United States Code are references to provisions of ARRA, and any reference to provisions of ARRA in the Contract or this BAA shall be deemed a reference to that provision and its existing and future implementing regulations, when and as each is effective. “Compliance Date” shall mean, in each case, the date by which compliance is required under the referenced provision of ARRA.

Section 2. **Effect.** This BAA shall apply to any PHI subject to the CCA and to any PHI provided by Covered Entity in the process of using data collection tools stored and maintained by XXX for purposes of Covered Entity’s participation in provision of patient care. Any provision of the CCA, including all exhibits or other attachments thereto and all documents incorporated therein by reference, that is directly contradictory to one or more terms of this BAA (“Contradictory Term”), shall be superseded by the terms of this BAA to the extent and only to the extent of the contradiction and only to the extent that it is reasonably impossible to comply with both the Contradictory Term and the terms of this BAA.

# RESPONSIBILITIES OF XXX

Section 1. **Use and Disclosure of Protected Health Information.** Except as otherwise specified herein, (1) if XXX and Covered Entity have not entered into a Memorandum of Understanding or CCA, the covered entity will not access, use or disclose the PHI entered into any tools or instruments by Covered Entity for any purpose other than the provision of that functionality, such as routine server maintenance, as otherwise necessary to fulfill its obligations under this BAA, or as Required By Law, (2) if XXX and Covered Entity have entered or enter into a Memorandum of Understanding or CCA, XXX may make any and all uses and disclosures of PHI necessary to perform its obligations under the CCA and this BAA, and (3) in any event, XXX may:

* 1. use and/or disclose PHI only as permitted or required by the CCA, this BAA, or as Required By Law, and in compliance with each applicable requirement of 45 C.F.R. § 164.504(e);
  2. use the PHI in its possession for its proper management and administration and to fulfill any legal responsibilities of XXX;
  3. disclose PHI in its possession to a third party for the purpose of XXX’s proper management and administration or to fulfill any legal responsibilities of XXX, provided however, that the disclosures are required by law or XXX has received from the third party written assurances that (i) the information will be held confidentially and be used or further disclosed only as required by law or for the purposes for which it was disclosed to the third party, and (ii) the third party will notify XXX (and, in accordance with Article II, Section 3 of this BAA, XXX shall notify Covered Entity) of any instances of which it becomes aware in which the confidentiality of the information has been breached;
  4. de-identify any and all PHI obtained by or for either party under this BAA and/or the CCA, and use and/or disclose such de-identified data on XXX’s own behalf, all in accordance with the de-identification requirements of the Privacy Regulations.

XXX shall use and/or disclose the minimum amount of PHI necessary with regard to its use and/or disclosure of PHI under this Section 1, provided, that XXX shall comply with 42 U.S.C. § 17935(b) as of its Compliance Date. All other uses and disclosures of PHI not authorized by this BAA or the CCA are prohibited.

Section 2. **Appropriate Safeguards.** XXX will use appropriate administrative, technical and physical safeguards to prevent the use or disclosure of PHI, other than as provided for by the CCA, this BAA or as required by law. As of the Compliance Date of 42 U.S.C. § 17931, XXX will comply with the Security Rule requirements set forth in 45 C.F.R. §§ 164.308, 164.310, 164.312, and 164.316, including implementing administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity. XXX will also keep current and document such security measures in written policies, procedures or guidelines, and make its policies and procedures, and documentation required by the Security Rule relating to such safeguards, available to the Secretary of the Department of Health and Human Services (“HHS”) for purposes of determining Covered Entity’s compliance with the Security Regulations.

Section 3. **Reporting of Improper Use or Disclosure of PHI.** XXX and/or the Covered Entity will, within ten (10) business days of becoming aware of any use or disclosure of PHI not permitted or required by the CCA or this BAA or of any Security Incident with respect to Electronic PHI of which it becomes aware, report such use, disclosure or Security Incident to Covered Entity and/or XXX, whichever is applicable. XXX and/or the Covered Entity agrees to mitigate, to the extent practicable, any harmful effect that is known of a use or disclosure of PHI by either party in violation of the requirements of this BAA. XXX further agrees to report without unreasonable delay and in no case later than sixty (60) calendar days after discovery, any Breach of any Unsecured PHI in accordance with the security breach notification requirements set forth in 42 U.S.C. § 17932 as of its Compliance Date.

Section 4. **Subcontractors and Agents.** XXX and/or the Covered Entity agree that any time PHI is provided or made available to its subcontractors or agents, XXX and/or the Covered Entity will enter into an agreement with the subcontractor or agent that contains the same conditions and restrictions on the use and disclosure of PHI as contained in the CCA and this BAA, and will ensure that all of its subcontractors and agents to whom it provides Electronic PHI agree to implement reasonable and appropriate safeguards to protect such Electronic PHI.

Section 5. **Right of Access, Amendment and Accounting of Disclosures**. With respect to the PHI in XXX’s possession, XXX agrees to the following: within a) within fifteen (15) calendar days of receiving a written request from Covered Entity, XXX will make available to Covered Entity information necessary for the Covered Entity to make an Accounting of Disclosures of PHI about an Individual in accordance with the Privacy Regulations as set forth in 45 C.F.R. Section 164.528 and, as of its Compliance Date, in accordance with the requirements for Accounting for Disclosures made through an Electronic Health Record in 42 U.S.C. 17935(c), and when directed by Covered Entity, XXX shall make that accounting directly to the Individual.

1. XXX shall record the following information regarding each disclosure of PHI subject to an Accounting of Disclosures pursuant to 45 C.F.R.Section 164.528:
2. date of disclosure;

2) name of entity or person who received the PHI and, if known, the address of such entity or person;

(3) a brief description of the PHI; and

(4) a brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or a copy of a written request for disclosure. For multiple such disclosures of PHI to the same person or entity for a single purpose, XXX shall provide Covered Entity, pursuant to Article II, Section 5(a) of this BAA, (1) the information set forth in Article II, Section 5(b) of this BAA regarding the first disclosure; (2) the frequency, periodicity or number of disclosures made during the accounting period; and (3) the date of the last such disclosure during the accounting period.

As of the Compliance Date, XXX shall also record any required information regarding each disclosure of PHI through an Electronic Health Record subject to an Accounting of Disclosures pursuant to 42 U.S.C. 17935(c);

1. within ten (10) calendar days of receiving a written request from Covered Entity, make available PHI necessary for Covered Entity to respond to individuals’ requests for access to PHI about them in the event that the PHI in XXX’s possession constitutes a Designated Record Set in accordance with the Privacy Regulations at 45 C.F.R. Section 164.524;
2. In the event that XXX, on behalf of Covered Entity, in connection with the CCA uses or maintains an Electronic Health Record of information of or about an Individual, then XXX shall provide an electronic copy (at the request of Covered Entity, and in the time and manner designated by Covered Entity) of the PHI, to Covered Entity, so that Covered Entity may comply with an Individual’s request in accordance with 42 U.S.C. § 17935(e) as of its Compliance Date;
   1. within fifteen (15) calendar days of receiving a written request from Covered Entity, incorporate any Amendments or corrections to the PHI in accordance with the Privacy Regulations at 45 C.F.R. Section 164.526 in the event that the PHI in XXX’s possession constitutes a Designated Record Set;
   2. make available its internal practices, books, and records relating to the use and disclosure of PHI to the Secretary of the United States Department of Health and Human Services (“HHS”) for purposes of determining Covered Entity’s compliance with the Privacy Regulations; and
   3. forward to Covered Entity within five (5) business days of receiving any requests an Individual makes of XXX pursuant to 45 C.F.R. Sections 164.524, or 164.526, so that Covered Entity may respond to such requests. XXX shall not respond directly to those Individual requests.

Section 6. **Exchange of PHI and Communications.** XXX and Covered Entity agree to the following:

1. shall not directly or indirectly receive remuneration in exchange for any PHI in compliance with 42 U.S.C. § 17935(d) as of its Compliance Date;
2. shall not make or cause to be made any communication about a product or service that is prohibited by 42 U.S.C. § 17936(a) as of its Compliance Date;
3. shall not make or cause to be made any written fundraising communication that is prohibited by 42 U.S.C. § 17936(b) as of its Compliance Date.

# OBLIGATIONS OF COVERED ENTITY

Section 1. **Limitations on Protected Health Information.** Covered Entity agrees that it will not furnish to XXX any PHI that is subject to any restrictions on the use and/or disclosure of PHI as provided for in 45 C.F.R. Section 164.522 that will affect XXX’s use or disclosure of the PHI under this BAA; provided that with respect to restrictions that Covered Entity is required to agree to under 42 U.S.C. § 17935(a) as of its Compliance Date, Covered Entity shall provide XXX with clear written notice of those restrictions and the PHI to which they pertain.

Section 2. **Consent and Authorization.** Covered Entity agrees to obtain any consent, authorization or permission that may be required by the Privacy Regulations or applicable state and federal laws and/or regulations prior to furnishing XXX the PHI pertaining to an Individual for the purposes set forth in this BAA.

Section 3. **Compliance with HIPAA and ARRA**. Covered Entity in performing its obligations and exercising its rights under this Agreement shall use and disclose Protected Health Information in compliance with the Privacy Rule, Security Rule and ARRA.

Section 4. **Covered Entity Requests**. Covered Entity shall not request or require Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule, Security Rule or ARRA if done by Covered Entity, provided that Business Associate may use or disclose PHI as set forth in Section 1. (d), (e) & (f) of Article II of this BAA.

# TERMINATION OF AGREEMENT

Section 1. **Termination of Agreement by Covered Entity.** Upon Covered Entity’s knowledge of a breach of a material term of this BAA by XXX, Covered Entity shall provide XXX with written notice of that breach in sufficient detail to enable XXX to understand the specific nature of that breach and afford XXX the opportunity to cure the breach; provided, however, that if XXX fails to cure the breach within a reasonable time specified by Covered Entity, Covered Entity may terminate this BAA or, if termination is not feasible, report the

breach to HHS. Upon termination of this BAA under this Section, XXX will comply with the return or destruction provisions of Article IV, Section 3 below, and Covered Entity may terminate the CCA, unless the Parties mutually agree that XXX may review Covered Entity pursuant to the CCA with information that has been de-identified in accordance with the Privacy Regulations. If after termination of this BAA pursuant to this Section the parties agree that XXX will continue its review of Covered Entity under the CCA using de-identified information, the Contract shall continue in effect and the terms of this BAA that apply to such review of Covered Entity pursuant to the Contract shall survive to the extent necessary for XXX to fulfil its patient care objectives.

Section 2. **Termination of Agreement by XXX.** In accordance with 42 U.S.C. § 17934(b) as of its Compliance Date, upon XXX’s knowledge of a breach of a material term of this BAA by Covered Entity, XXX shall provide Covered Entity with written notice of that breach in sufficient detail to enable Covered Entity to understand the specific nature of that breach and afford Covered Entity the opportunity to cure the breach; provided, however, that if Covered Entity fails to cure the breach within a reasonable time specified by XXX, XXX may terminate this BAA as well as terminate the Contract or, if termination is not feasible, report the breach to HHS.

Section 3. **Return or Destruction of PHI.** Within thirty (30) calendar days after termination or expiration of the Contract or this BAA, XXX agrees to either return to Covered Entity or destroy all PHI received from the Covered Entity or created or received by XXX on behalf of the Covered Entity and which XXX still maintains in any form, including such information in possession of XXX’s subcontractors. XXX such PHI. If return or destruction of the PHI is not feasible, XXX agrees to extend the protections, limitations and restrictions of this BAA to XXX’s use and disclosure of PHI retained after termination and to limit any further uses or disclosures to the purposes that make return or destruction infeasible. Any de-identified information retained by XXX shall not be re-identified except for a purpose permitted under this BAA.

# INDEMNIFICATION

Section 1. **Mutual Indemnification.** Each party will indemnify, hold harmless and defend the other party to this BAA from and against any and all claims, losses, liabilities, costs and other expenses, including reasonable attorney’s fees, incurred as a result of, or arising directly out of or in connection with: (i) any misrepresentation or non-fulfillment of any undertaking on the part of the party pursuant to this BAA; and (ii) any claims, demands, awards, judgments, actions and proceedings made by any person or organization arising out of or connected with the party’s performance under this BAA, provided however, a party’s liability hereunder shall be limited to recovery of actual compensatory damages in an amount not to exceed amounts paid by XXX under the CCA. In no event will a party be responsible for any damages caused by the failure of the other party to perform its responsibilities or other consequential, special, incidental, indirect, exemplary, or punitive damages, even if such party has been advised of the possibility of such damages.

# LIMITATION OF LIABILITY

Section 1. **DAMAGES.** NO PARTY SHALL BE LIABLE TO ANOTHER PARTY HERETO FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY KIND OR NATURE RELATING TO OR ARISING FROM THE PERFORMANCE OR BREACH OF OBLIGATIONS SET FORTH IN THIS BAA, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

# MISCELLANEOUS

Section 1. **Choice of Law and Jurisdiction.** The law of the State of Maine shall govern this BAA. The parties agree that any dispute arising under this BAA shall only be resolved in a court of competent jurisdiction in the State of Maine.

Section 2. **Change in Law.** The parties agree to negotiate to amend this BAA (a) as necessary to comply with any amendment to any provision of HIPAA or its implementing regulations, ARRA, or to comply with any other applicable laws or regulations, or amendments thereto, and/or (b) in the event any such law or regulation or amendment thereto materially alters either party or both parties’ obligations under this BAA. The parties agree to negotiate in good faith mutually acceptable and appropriate amendment(s) to this BAA to give effect to such revised obligations. If the parties are unable to agree to mutually acceptable amendment(s) within sixty (60) calendar days of the relevant change in law or regulations, either party may terminate this BAA and the CCA consistent with the terms of this BAA and the CCA.

Notwithstanding the preceding sentence, the parties agree that this BAA is written to encompass ARRA and its implementing regulations.

Section 3. **Third Party Beneficiaries.** Nothing in this BAA shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

Section 4. **Survival.** Article I; Article II; Article IV, Section 3; and Articles V, VI, and VIII of this BAA shall survive termination of this BAA. The last sentence of Article IV Section 1 shall survive termination of this BAA with regard to any de-identified information created by either party using PHI.

Section 5. **Notice.** Any notice, consent, request or waiver, or other communications to be given hereunder by either party shall be given in writing and will be deemed to have been given when delivered personally or by registered mail, postage prepaid and return receipt requested or by email with a confirming copy placed in the United States mail addressed as provided below or to such other address as either party may designate by written notice to the other.

If to XXX (Legal Name of Practice):

xxx, Administrator

Street Address

Town/City, State Zip

Email:

If to Covered Entity:

Legal Name of Contractor

c/o Authorized Name of Signatory, Title

Street Address

Town/City, State, Zip

Email:

**Covered Entity**:

Name of Individual/Entity:

By:

# Title:

# Date:

# Name of Practice

By:

Title:

Date:

**Dragatsi & Co. does not take responsibility for any outcomes using this template. It is advised that review by an authorized attorney be utilized by the pharmacist before submission to other signatories to the agreement, and before submission for Board approval or any other certifying body.**