

Erie County Medical Center Corporation

BUSINESS ASSOCIATE CONFIDENTIALITY AGREEMENT

THIS AGREEMENT (the "Agreement") is made this ____ day of August , 2005 by and between Erie County Medical Center Corporation, located at 462 Grider Street, Buffalo, New York 14215 (herein, "ECMCC"), and The Research Foundation of State University of New York, a private, non-profit educational corporation with a local address at 211 UB Commons, Buffalo, New York 14260 (herein, "BUSINESS ASSOCIATE").

WITNESSETH:

WHEREAS, ECMCC is a healthcare provider required by law to maintain reasonable and appropriate administrative, technical and physical safeguards to ensure the integrity and confidentiality of health care information; and

WHEREAS, under the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations (known as the "Privacy Rule"), business associates must agree in writing to provisions applicable to the use and disclosure of protected health information ("Protected Health Information" or "PHI"); and

WHEREAS, ECMCC periodically receives requests by Researchers (hereinafter defined) for certain patient data, which may include PHI as defined in the Privacy Rule, in connection with Research, as defined in the Privacy Rule, conducted by such Researchers; and

WHEREAS, BUSINESS ASSOCIATE has agreed to extract information from PHI created or maintained by ECMCC to create Research Data Sets (hereinafter defined) to enable

ECMCC to disclose Research Data Sets to Researchers and, upon request, to possibly assist ECMCC in fulfilling such disclosure requests, all in accordance with HIPAA;

NOW, THEREFORE, in consideration of the terms and conditions contained herein and intending to be legally bound hereby, the parties hereto agree as follows:

1. **DEFINITIONS:** For purposes of this Agreement, terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the 42 CFR part 160 subpart A, 42 CFR part 164 subparts A, C (the “HIPAA Security Rule”) and E (the “HIPAA Privacy Rule”):
 - a) **Business Associate.** "BUSINESS ASSOCIATE" shall be limited to mean The Research Foundation of State University of New York and employees and authorized agents of BUSINESS ASSOCIATE who are specifically assigned to create Research Data Sets, utilizing PHI created or maintained by ECMCC under this Agreement. Such employees and authorized agents will be listed on Schedule A, attached hereto, as may be amended from time to time.
 - b) **Covered Entity.** "Covered Entity" shall mean ECMCC.
 - c) **Protected Health Information.** "Protected Health Information" or “PHI” shall be as it is defined at 45 C.F.R § 160.103, and includes Electronic Protected Health Care Information as defined in 45 CFR § 160.103.
 - d) **Researchers.** “Researchers” means any person, individual, corporation, company, association, entity or group of individuals performing one or more bona fide systematic investigations, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, as defined in 45 CFR § 160.501.

e) Research Data Set(s). “Research Data Set(s)” means certain patient data which has been prepared by BUSINESS ASSOCIATE pursuant to this Agreement from data created or maintained by ECMCC, and which is to be used by or disclosed to Researchers for the conduct of Research. Research Data Sets may include any PHI created or maintained by ECMCC, limited data sets, or de-identified information, all as defined in the Privacy Rule. A Research Data Set created under this Agreement is specifically designated as being distinct and separate from the ECMCC Designated Record Sets as defined in 45 C.F.R § 164.501. As such, a Research Data Set is not subject to individual rights of access as defined in 45 C.F.R § 164.524 and is not subject to individual rights of amendment as defined in 45 C.F.R § 164.526.

2. **BUSINESS ASSOCIATE SERVICES:** BUSINESS ASSOCIATE, in accordance with this Agreement, agrees to perform one or more of the following services on behalf of the Covered Entity; (i) extraction of certain PHI created or maintained by ECMCC and creation of Research Data Sets to enable ECMCC to disclose those Research Data Sets to Researchers; and (ii) upon request, to assist ECMCC by fulfilling such disclosure requests from Researchers and maintaining the information required for ECMCC to account for disclosures per 45 C.F.R § 164.528, all in accordance with HIPAA and the terms of this Agreement.

3. **BUSINESS ASSOCIATE ASSURANCES:** BUSINESS ASSOCIATE agrees to abide by HIPAA’s requirements applicable to business associates and business associate contracts and, further assures ECMCC that (i) BUSINESS ASSOCIATE will appropriately safeguard PHI made available to or obtained by BUSINESS ASSOCIATE

as required by law and (ii) BUSINESS ASSOCIATE will, as required by law, implement reasonable and appropriate administrative, physical and technical safeguards as are necessary to protect the confidentiality, integrity and availability of PHI created, received, maintained or transmitted on behalf of ECMCC under the terms of this Agreement. BUSINESS ASSOCIATE hereby agrees to comply with applicable requirements of law relating to PHI and with respect to any task or other activity BUSINESS ASSOCIATE performs on behalf of ECMCC under the terms of this Agreement to the extent ECMCC would be required to comply with such requirement or otherwise pursuant to this Agreement.

4. RESTRICTIONS ON USE: BUSINESS ASSOCIATE agrees that it will:
- a) Use reasonable efforts to only use or disclose the minimum necessary PHI required to perform the activities covered by this Agreement.
 - b) Not use or further disclose PHI other than as permitted or required by this Agreement or as required by law;
 - c) Use appropriate administrative, technical and physical safeguards to prevent use or disclosure of PHI as required by law;
 - d) Take steps, to the extent practicable, to reduce or eliminate any harmful effect that is known to BUSINESS ASSOCIATE arising from a violation of the requirements of applicable law or this Agreement;
 - e) Report to ECMCC any use or disclosure of PHI associated with activities covered in this Agreement that are not provided for by this Agreement, or any breach of security, as soon as practicable upon discovery by BUSINESS ASSOCIATE;

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- f) Ensure that any permitted subcontractors or agents to whom BUSINESS ASSOCIATE provides PHI under this Agreement agree to the same restrictions and conditions that apply to BUSINESS ASSOCIATE with respect to such PHI;
 - g) Forward to ECMCC all individual or third-party requests for PHI, including without limitation, all subpoena requests for PHI, associated with BUSINESS ASSOCIATE activities under this Agreement that are received by BUSINESS ASSOCIATE within two (2) business days of receipt, or such shorter deadline as may appear in a subpoena or as otherwise required by law;
 - h) Make internal practices, books, and records of BUSINESS ASSOCIATE relating to the use and disclosure of PHI received from, or created or received by BUSINESS ASSOCIATE on behalf of ECMCC under the terms of this Agreement available upon reasonable request to ECMCC and the Secretary of the U.S. Department of Health and Human Services at no charge for the purpose of determining ECMCC's compliance with the Privacy Rule (in all events, BUSINESS ASSOCIATE shall immediately notify ECMCC upon receipt by BUSINESS ASSOCIATE of any such request by the Secretary, and shall provide ECMCC with copies of any such materials);
 - i) Make available and incorporate any amendment(s), as required by 45 CFR § 164.526, to PHI contained in a Designated Record Set maintained by the BUSINESS ASSOCIATE on behalf of ECMCC for the performance of activities under this Agreement that ECMCC reasonably directs in the time and manner designated by ECMCC;

- j) Provide access to an Individual to inspect and obtain a copy of PHI about the Individual contained in a Designated Record Set maintained by the BUSINESS ASSOCIATE on behalf of ECMCC for the performance of activities under this Agreement as required by 45 CFR § 164.524;
- k) In addition to the requirements set forth in Section 5 of this Agreement, when releasing a Research Record Set to a Researcher at the request of ECMCC, document and make available to ECMCC disclosures of PHI (if any) and information related to such disclosures as would be required for ECMCC to respond to a request by an Individual for an accounting and as otherwise required by 45 CFR § 164.528;
- l) Permit ECMCC, on reasonable notice to BUSINESS ASSOCIATE, to audit BUSINESS ASSOCIATE, at ECMCC sole expense, the books, records, and systems of BUSINESS ASSOCIATE relating to the use and disclosure of PHI on behalf of Covered Entity under this Agreement and the implementation of appropriate security safeguards to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528;
- m) At termination of this Agreement, if feasible, return to ECMCC or destroy all PHI received from, or created or received by BUSINESS ASSOCIATE on behalf of ECMCC under this Agreement that BUSINESS ASSOCIATE maintains in any form, or if not feasible, then the provisions of this Agreement protecting PHI shall be perpetual and shall continue to apply until such PHI is returned or destroyed.

5. USE AND DISCLOSURE OF PHI FOR RESEARCH: Upon request from a Researcher for PHI, ECMCC will provide certain Research Data Set(s) to such Researcher, provided one of the following criteria are satisfied to ECMCC's reasonable satisfaction:
- a) ECMCC receives Authorizations from each Individual for research as specified under 45 CFR § 164.508;
 - b) ECMCC receives documentation of an IRB's or a Privacy Board's waiver of the Authorization requirement as specified in 45 CFR § 164.512 (i);
 - c) ECMCC receives documentation of an IRB's or a Privacy Board's alteration of the Authorization requirement and the altered Authorizations from the individuals;
 - d) the Researcher receives a Limited Data Set pursuant to a signed Data Use Agreement with ECMCC as specified under 45 CFR § 164.514(e); or
 - e) the Researcher receives De-Identified information as specified in 45 CFR § 164.514 (a) through (c);
 - f) the Researcher receives PHI in a manner consistent with the Transition Provisions of HIPAA as specified in 45 CFR § 164.532 (c);
 - g) ECMCC receives written representations from the Researcher (i) that the use or disclosure of PHI is solely to prepare a Research protocol or for similar purposes preparatory to research; (ii) that the Researcher will not remove any PHI from ECMCC; and (iii) that PHI for which access is sought is necessary for the Research purpose [45 CFR §164.512(i)(1)(ii)];
 - h) The Researcher provides ECMCC with documentation of the death of such individuals whose PHI is sought by the Researcher, and ECMCC receives written

representations from the Researcher (i) that the use or disclosure being sought is solely for Research on PHI of decedents; and (ii) that the PHI being sought is necessary for the Research [45 CFR §164.512 (i)(1)(iii)].

Notwithstanding the above, ECMCC may reasonably condition disclosure of PHI to a Researcher upon receipt from the Researcher of written representations that it will limit its use and disclosure to the minimum necessary amount.

6. **TERMINATION**: If ECMCC reasonably determines that BUSINESS ASSOCIATE has violated a material term of this Agreement, ECMCC may terminate this Agreement upon 30 day's written notice without penalty or recourse; provided ECMCC agrees to give BUSINESS ASSOCIATE written notice of such default and provide BUSINESS ASSOCIATE an opportunity to take appropriate steps to correct such default.

Notwithstanding the above, ECMCC may immediately limit or terminate rights of any employee(s) or agent(s) of BUSINESS ASSOCIATE responsible for such violations to access ECMCC's premises or PHI under this Agreement, without penalty or recourse.

7. **INDEMNIFICATION**: BUSINESS ASSOCIATE agrees to indemnify, defend and hold harmless ECMCC, its affiliates and their respective directors, officers, employees and agents, from and against any costs, expenses, liabilities, losses, damages, injunctions, suits, fines, penalties, claims and demands of every kind or nature, including without limitation, those related to personal injury and death, reasonable counsel fees and court costs, sought by or on behalf of any person, party or governmental agency or subdivision arising out of or related to BUSINESS ASSOCIATE's negligent acts or omissions arising out of the performance of this Agreement.

8. AMENDMENTS: BUSINESS ASSOCIATE agrees that this Agreement may be amended from time to time by ECMCC if and to the extent required by HIPAA and its regulations, in order to assure that this Agreement is consistent with such law and regulations. This Agreement may not be amended orally or by a course of conduct pursued by ECMCC or BUSINESS ASSOCIATE, but may be amended only in a writing duly authorized by the parties hereto.

9. NOTICE: All notices or other communications required or permitted to be given pursuant to this Agreement shall be given in writing by personal delivery or certified mail, postage prepaid, to the parties at the following addresses:

If to ECMCC:
Erie County Medical Center Corporation
462 Grider Street
Buffalo, New York 14215
Attention: Corporate Compliance Officer

If to BUSINESS ASSOCIATE:
University at Buffalo
211 UB Commons
Buffalo, NY 14260
Attention: Assistant Vice President for Sponsored Programs Administration

AND

University at Buffalo
173 Biomedical Education Building
3435 Main Street
Buffalo, NY 14214
Attention: University at Buffalo Director of HIPAA Compliance

or such other addresses as may be provided in writing pursuant to this Agreement.

10. ASSIGNMENT: This Agreement obligates ECMCC and BUSINESS ASSOCIATE and their respective successors and permitted assignees. No party may assign this

Agreement, in whole or in part, without the prior written consent of the other party, which consent may be withheld or delayed for any or no reason.

11. APPLICABLE LAW: This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without regard to principles of conflicts of law.

IN WITNESS WHEREOF, the parties have executed this Agreement the day and year first above written.

ERIE COUNTY MEDICAL CENTER CORPORATION

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK

By: _____

By: _____

Name: _____
(Please print/type.)

Name: _____
(Please print/type.)

Title: _____
(Please print/type)

Title: _____
(Please print/type)

Dated: _____

Dated: _____

APPROVED AS TO FORM

By: _____
Anthony J. Colucci, III
ECMCC Attorney

Dated: _____