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BUSINESS ASSOCIATE AGREEMENT

THIS AGREEMENT (the "Agreement") is made this 26th day of January, 2006 by and between Erie County Medical Center Corporation, located at 462 Grider Street, Buffalo, New York 14215 ("ECMCC"), and UB Foundation Activities, Inc., a New York not-for-profit corporation with a mailing address at Box 900, Buffalo, New York 14226-0900 ("BUSINESS ASSOCIATE").

WITNESSETH:

WHEREAS, ECMCC is a healthcare provider subject to the requirements of the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated pursuant thereto (collectively, "HIPAA") with respect to the use and disclosure of "Protected Health Information" by a "Covered Entity" as those terms are defined herein or in HIPAA; and

WHEREAS, ECMCC periodically receives requests from Researchers (as hereinafter defined) for certain patient data, which may include Protected Health Information in connection with research conducted by such Researchers; and

WHEREAS, BUSINESS ASSOCIATE, as a supporting organization of the State University of New York at Buffalo (the "University"), will participate in a project by providing support to persons extracting information from Protected Health Information created or maintained by ECMCC to create Research Data Sets (as hereinafter defined) to enable ECMCC to disclose Research Data Sets to Researchers and, upon request, assisting ECMCC in fulfilling such disclosure requests; and

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WHEREAS, by reason of such activities, ECMCC and BUSINESS ASSOCIATE believe that BUSINESS ASSOCIATE is a "business associate" of ECMCC, as such term is defined in HIPAA, resulting in the need for ECMCC and BUSINESS ASSOCIATE to enter into this Agreement as required by 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.

- a) Business Associate. "BUSINESS ASSOCIATE" shall be limited to mean UB Foundation Activities, Inc. solely with respect to persons (i) acting on behalf of the University for whom BUSINESS ASSOCIATE provides certain administrative services and (ii) who are specifically assigned by the University to perform the services described in Section 2 of this Agreement. Such persons will be listed on Schedule A attached hereto and made a part hereof.
- b) 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).
- c) Protected Health Information. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR 164.501, but shall be limited to the information received by BUSINESS ASSOCIATE from, or created or received by BUSINESS ASSOCIATE on behalf of, ECMCC pursuant to this Agreement.

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- d) Required by Law. "Required by Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.
- e) Researchers. "Researchers" means any person, individual, corporation, company, association, entity or group of individuals performing one or more systematic investigations, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, as defined in 45 C.F.R. 164.501.
- f) 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 purposes described in subpart (e) of this Section 1. Research Data Sets may include any Protected Health Information created or maintained by ECMCC, limited data sets, or de-identified information, all as defined in HIPAA. A Research Data Set created under this Agreement is specifically designated as being distinct and separate from ECMCC's Designated Record Sets as defined in 45 CFR 164.501. As such, a Research Data Set is not subject to Individual rights of access as defined in 45 CFR 164.524 and is not subject to Individual rights of amendment as defined in 45 CFR 164.526.

2. BUSINESS ASSOCIATE SERVICES. BUSINESS ASSOCIATE agrees to perform one or both of the following services on behalf of ECMCC: (i) extraction of certain Protected Health Information 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

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request, to assist ECMCC by fulfilling such disclosure requests from Researchers and maintaining the information required for ECMCC to account for disclosures pursuant to 45 CFR 164.528.

3. OBLIGATIONS OF BUSINESS ASSOCIATE. In connection with its performance of the services described in Section 2 of this Agreement, BUSINESS ASSOCIATE agrees that it will:

- a) Use reasonable efforts to use or disclose only the minimum necessary Protected Health Information required to perform the activities described in Section 2 of this Agreement.
- b) Not use or disclose Protected Health Information in any manner that would not be permissible under HIPAA if done by ECMCC.
- c) Not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required by Law;
- d) Use appropriate administrative, technical and physical safeguards to prevent use or disclosure of Protected Health Information other than as provided for in this Agreement;
- e) Mitigate, to the extent practicable, any harmful effect that is known to BUSINESS ASSOCIATE arising from use or disclosure of Protected Health Information by BUSINESS ASSOCIATE in violation of the requirements of this Agreement;

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- f) Report to ECMCC any use or disclosure of Protected Health Information not provided for by this Agreement of which BUSINESS ASSOCIATE becomes aware;
- g) Ensure that any permitted subcontractors or other agents to whom BUSINESS ASSOCIATE provides Protected Health Information received from, or created or received by BUSINESS ASSOCIATE on behalf of, ECMCC under this Agreement agree to the same restrictions and conditions that apply throughout this Agreement to BUSINESS ASSOCIATE with respect to such Protected Health Information;
- h) Forward to ECMCC, within two (2) business days of BUSINESS ASSOCIATE's receipt, or such shorter deadline as may appear in a subpoena or as otherwise required by law, all requests for Protected Health Information, including without limitation, all subpoena requests for Protected Health Information associated with BUSINESS ASSOCIATE's activities under this Agreement.
- i) Make the internal practices, books, and records of BUSINESS ASSOCIATE relating to the use and disclosure of Protected Health Information 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 or, at the request of ECMCC, to the Secretary of the U.S. Department of Health and Human Services (the "Secretary"), in the time and manner designated by the Secretary, for the purpose of the Secretary determining ECMCC's compliance with HIPAA. BUSINESS ASSOCIATE shall immediately notify ECMCC upon

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receipt by BUSINESS ASSOCIATE of any such request by the Secretary, and shall provide ECMCC with copies of any such request;

- j) In addition to the requirements set forth in Section 5 of this Agreement, when releasing a Research Data Set to a Researcher at the request of ECMCC, document and, at ECMCC's request, make available to ECMCC, disclosures of Protected Health Information and information related to such disclosures as would be required for ECMCC to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528;
- k) Permit ECMCC, on reasonable notice to BUSINESS ASSOCIATE and during BUSINESS ASSOCIATE's normal business hours, to audit, at ECMCC's sole expense, the books, records, and systems of BUSINESS ASSOCIATE relating to the use and disclosure of Protected Health Information on behalf of ECMCC under this Agreement to determine BUSINESS ASSOCIATE's compliance with the terms of this Agreement.
- l) Upon termination of this Agreement, if feasible, return to ECMCC or destroy all Protected Health Information received from, or created or received by BUSINESS ASSOCIATE on behalf of, ECMCC under this Agreement that BUSINESS ASSOCIATE maintains in any form. If such return or destruction is not feasible, BUSINESS ASSOCIATE shall limit further uses of such Protected Health Information to those purposes that make the return or destruction infeasible and the provisions of this Agreement protecting Protected Health Information shall

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continue to apply until such Protected Health Information is returned to ECMCC or destroyed.

4. USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH. Upon request from a Researcher for Protected Health Information, ECMCC, or BUSINESS ASSOCIATE, at the request of ECMCC, will provide certain Research Data Set(s) to such Researcher. Before ECMCC provides, or requests BUSINESS ASSOCIATE to provide, any Research Data Sets to a Researcher, ECMCC shall determine to its reasonable satisfaction that one of the following criteria is satisfied:
- a) ECMCC receives authorizations from each Individual as specified under 45 CFR 164.508;
 - b) ECMCC receives documentation of a waiver by an Institutional Review Board, as defined in 45 CFR 164.512(i)(1)(A) (an "IRB"), or a Privacy Board (as defined in 45 CFR 164.512(i)(1)(B)), 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 each Individual;
 - 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);
 - e) the Researcher receives de-identified information as specified in 45 CFR 164.514 (a) through (c);

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- f) the Researcher receives Protected Health Information in a manner consistent with the Transition Provisions of HIPAA as specified in 45 CFR 164.532 (c);
- g) as described in 45 CFR 164.512(i)(1)(ii), ECMCC receives written representations from the Researcher (i) that the use or disclosure of Protected Health Information is solely to prepare a research protocol or for similar purposes preparatory to research; (ii) that the Researcher will not remove any Protected Health Information from ECMCC; and (iii) that Protected Health Information for which access is sought is necessary for the research purpose; or
- h) as described in 45 CFR 164.512(i)(1)(iii), the Researcher provides ECMCC with documentation of the death of each Individual whose Protected Health Information 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 Protected Health Information of decedents; and (ii) that the Protected Health Information being sought is necessary for the research.

Notwithstanding the foregoing, ECMCC may reasonably condition disclosure of Protected Health Information to a Researcher upon receipt from the Researcher of written representations that it will limit its use and disclosure of such Protected Health Information to the minimum necessary for the conduct of the research.

5. OBLIGATIONS OF ECMCC.

- a) ECMCC shall notify BUSINESS ASSOCIATE of any limitations in ECMCC's notice of privacy practices in accordance with 45 CFR 164.520 to the extent that

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such limitation may affect BUSINESS ASSOCIATE's use or disclosure of Protected Health Information.

- b) ECMCC shall provide BUSINESS ASSOCIATE with any changes in, or revocation of, permission by an 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, and to the extent known by ECMCC.
- c) ECMCC shall notify BUSINESS ASSOCIATE of any restriction on the use or disclosure of Protected Health Information that ECMCC 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.
- d) ECMCC shall not request that BUSINESS ASSOCIATE use or disclose Protected Health Information in any manner that would not be permissible under HIPAA if done by ECMCC.
- e) Notwithstanding the provisions of subpart (b) of Section 3 and subpart (d) of this Section 5 and except as otherwise limited by this Agreement, BUSINESS ASSOCIATE (i) may use Protected Health Information for the proper management and administration of BUSINESS ASSOCIATE or to carry out its legal responsibilities; (ii) may disclose Protected Health Information for the proper management and administration of BUSINESS ASSOCIATE, provided that such disclosures are Required by Law, or BUSINESS ASSOCIATE obtains reasonable assurances from the person to whom the information is disclosed that

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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 BUSINESS ASSOCIATE of any instances of which it is aware in which the confidentiality of the information has been breached; and (iii) may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

6. TERM AND TERMINATION.

- a) Term. The term of this Agreement shall commence on the date shown at the beginning of this Agreement and, subject to the requirements of Section 3(1) of this Agreement, shall terminate upon delivery of a written notice of termination by either party. Without limiting the foregoing, BUSINESS ASSOCIATE may terminate this Agreement when all of the Protected Health Information provided by ECMCC to BUSINESS ASSOCIATE, or created or received by BUSINESS ASSOCIATE on behalf of ECMCC, is destroyed, conveyed to Researchers according to the terms of this Agreement, or returned to ECMCC.

- b) Termination for Cause. Upon ECMCC's knowledge of a material breach of this Agreement by BUSINESS ASSOCIATE, ECMCC may, in its sole discretion, either (i) provide BUSINESS ASSOCIATE with a written notice that identifies the breach, give BUSINESS ASSOCIATE 30 days to cure the breach and terminate this Agreement if BUSINESS ASSOCIATE does not cure the breach within the 30-day period or (ii) terminate this Agreement immediately.

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7. AMENDMENTS. 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. Subject to the requirements of the preceding sentence, the parties agree to take such action to amend this Agreement from time to time as is necessary for ECMCC to comply with the requirements of HIPAA.
8. REGULATORY REFERENCES. A reference in this Agreement to a section of the regulations promulgated pursuant to HIPAA shall mean that section as in effect or as amended.
9. INTERPRETATION. Any ambiguity in this Agreement shall be resolved to permit ECMCC to comply with HIPAA.
10. NOTICE. All notices or other communications required or permitted to be given pursuant to this Agreement shall be given in writing by personal delivery, telecopier or certified mail, postage prepaid, or by overnight express courier 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
Fax Number: (716) 898-5178

AND

Anthony J. Colucci, III
Colucci & Gallaher, P.C.
2000 Liberty Building
424 Main Street
Buffalo, New York 14202

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If to BUSINESS ASSOCIATE:

UB Foundation Activities, Inc.
Box 900
Buffalo, NY 14226-0900
Attention: Executive Director
Fax Number: (716) 645-3475

AND

Hodgson Russ LLP
One M&T Plaza, Suite 2000
Buffalo, NY 14203
Attention: Kathleen A. Wall, Esq.
Fax Number: (716) 849-0349

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

11. 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. Notwithstanding the foregoing, BUSINESS ASSOCIATE may assign its rights and obligations under this Agreement to its affiliate UB Foundation Services, Inc. in order to facilitate the objectives of the parties under this Agreement, provided that it complies with Section 3(g) hereof.

12. APPLICABLE LAW, VENUE. 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. Jurisdiction of any litigation with respect to this Agreement shall be in New York, with venue in a court of competent jurisdiction located in Erie County.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date shown at the beginning of this Agreement.

ERIE COUNTY MEDICAL CENTER CORPORATION

UB FOUNDATION ACTIVITIES, INC.

By: [Redacted]

By: [Redacted]

Name: Michael A Young
(Please print/type)

Name: Edward P. Schneider
(Please print/type)

Title: CSO
(Please print/type)

Title: Executive Director
(Please print/type)

Dated: 2-10-06

Dated: January 23, 2006

APPROVED AS TO FORM

By: [Redacted]
Anthony J. Corcoran, III
ECMCC Attorney

Dated: 1/26/06