BUSINESS ASSOCIATES

PURPOSE

To establish guidelines for UCLA Health to comply with the Privacy & Security Rule requirements relating to business associate relationships, including the entering into of business associate agreements (and amendments).

This policy applies to the UCLA Health System and David Geffen School of Medicine at UCLA (hereafter referred to as “UCLA Health”).

DEFINITIONS

“Protected Health Information” or “PHI” is any individually identifiable health information, in any format, including verbal communications, regarding a patient created as a consequence of the provision of health care. “Individually identifiable” means that the health or medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient’s name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual’s identity. PHI includes patient billing and health insurance information and applies to a patient’s past, current or future physical or mental health or treatment.

“Electronic Protected Health Information” or “ePHI” is PHI that is transmitted by electronic media or is maintained in electronic media. For example, ePHI includes all data that may be transmitted over the Internet, or stored on a computer, a CD, a disk, magnetic tape or other media.

“Personal Information (PI)” as used in this policy is an individual’s first name or first initial and last name combined with any one of the following:

1. social security number,
2. driver's license number or California identification card number,
3. account number, credit, or debit card number, in combination with any required security code, access code, or password that would permit access to an individual's financial account,
4. medical information, or
5. health insurance information.

“Medical information” means any information, in either electronic or physical form, regarding an individual’s medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional, and which may be in the
possession of or derived from a health care provider, health care service plan, pharmaceutical company or contractor. “Health insurance information” means an individual's health insurance policy number or subscriber identification number, any unique identifier used by a health insurer to identify the individual, or any information in an individual’s application and claims history, including any appeals records. Medical information and health insurance information for patients are also considered to be PHI.

“Restricted Information” (as defined by UC Policy IS-3, Electronic Information Security) describes any confidential or Personal Information that is protected by law or policy and that requires the highest level of access control and security protection, whether in storage or in transit. This includes Personal Information, PHI and ePHI as defined in this section but could also include other types of information such as research data.

“Workforce” includes employees, medical staff and other health care professionals, volunteers, agency, temporary, registry, and housestaff, students, and interns (regardless of whether they are UCLA trainees or rotating through UCLA Health System facilities from another institution).

POLICY

The Privacy & Security Rules permit providers such as UCLA Health to share health information with their contractors for purposes of “treatment, payment and health care operations” (“TPO”). The Privacy and Security Rules business associate provisions seek to ensure that these third parties adhere to the basic protections imposed by the Privacy and Security Rules and that there is no degradation of privacy and security safeguards when PHI is shared with business partners.

The Privacy and Security Rules require that all contracts between UCLA Health with business associates, who by definition receive protected health information (“PHI”) as part of TPO, contain language-requiring adherence to the Privacy and Security Rules guidelines. The Security Rule requires that Business Associates who receive, transmit, maintain or create PHI in an electronic format must sign an additional agreement to protect the confidentiality, integrity and availability of the electronic information.

It is the policy of UCLA Health that all such business associates must enter into a University of California-approved business associate agreement (or amendment).

I. Who is a Business Associate?

A business associate relationship exists when an individual or entity, acting on behalf of UCLA Health, assists in the performance of a function or activity involving the use or disclosure of PHI. This includes claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management or repricing.
Business associates may include any individual or entity that receives PHI from UCLA Health in the course of providing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, software support, or financial services. Business associates do not, however, include UCLA Health employees or other members of the UCLA Health Workforce.

(See Appendix A for common examples of business associate relationships.)

When UCLA Health or Workforce members perform business associate type functions for each other, no business associate amendment is required because all are considered to be a part of UCLA Health as one “covered entity” under the Privacy Rule and are subject to all of the Privacy Rule requirements and University of California System wide Standards and Implementation Policies.

II. Exceptions to the Business Associate Rules

A. Treatment.

The business associate rules do not apply to disclosures by UCLA Health to a health care provider for the purpose of treating the patient. Health care providers such as hospitals, physicians, medical groups, etc. are all subject to the Privacy Rule.

B. Financial Transactions.

A business associate contract is not required between a provider and a financial institution if the financial institution processes consumer financial transactions in payment for health care. Although some PHI of the patient may be disclosed to a financial institution, such as the patient’s identity and perhaps some health information (such as the procedure performed), these facts do not create a business associate relationship because the bank is not acting on behalf of UCLA Health System in performing its functions.

C. Organized Health Care Arrangements.

Under the Privacy Rule, an “organized health care arrangement” is a clinically integrated setting in which patients receive care from multiple health care providers. Providers participating in organized health care arrangements are not business associates of one another. Examples of organized health care arrangements may include hospital-medical staff arrangements and provider networks that engage in joint payment activities. However, each UCLA hospital and its respective medical staff do not constitute an organized health care arrangement.
D. Incidental Use.

There may be situations within UCLA Health where volunteers or contracted individuals have access to PHI that are not business associate relationships, but could provide incidental access to PHI—e.g., with outside entities who take newborn photos or clowns who entertain hospitalized children. To provide reasonable safeguards, UCLA Health may:

1. Require that those outside entities or persons sign a confidentiality agreement and receive information regarding the Privacy Rule; or

2. Require Privacy Rule training when UCLA Health’s volunteers and Workforce members carry out those activities.

III. Disclosure of PHI to Business Associates

UCLA Health may disclose PHI to its business associates for treatment, payment and health care operations without an authorization from the patient, if it has a business associate contract with the recipient. However, UCLA Health may disclose PHI to an entity in its role as a business associate only to help UCLA Health carry out its health care functions—not for the business associate’s independent use or purpose.

In addition, disclosures to business associates cannot be broader than UCLA Health could make internally or for purposes for which UCLA Health could not use or disclose the information itself.

A. Minimum Necessary.

If the disclosure is for payment or health care operations (as is usually the case), it is subject to the minimum necessary rule (See: Privacy Policy and Procedure No. 9401, “Protection of Confidential Patient Information (Protected Health Information)”, and must be restricted to the information necessary to enable the business associate to perform the function with which it is assisting UCLA Health System.

B. Authorization May be Required.

If UCLA Health would need the individual’s authorization to use the information (See: Privacy Policy and Procedure No. 9412, “Authorization for Use/Disclosure of Protected Health Information (PHI),” it would
similarly need the individual’s authorization to disclose the information to a business associate for the same purpose.

C. **Special Restrictions.**

If the use or disclosure of health information is specially restricted, the restrictions may preclude the disclosure to a business associate. For example, the Privacy Rule specifically restricts the use of psychotherapy notes – as a general rule. This would in most instances preclude disclosure of psychotherapy notes to a business associate without patient authorization. Limitations on disclosure or use may also apply to PHI concerning treatment for mental health or developmental disabilities, substance abuse, or HIV results.

IV. **Business Associate Agreements**

UCLA Health must enter into University-approved business associate agreements (or amendments) with its business associates and obtain documented satisfactory assurance that the business associate will appropriately safeguard any PHI provided under the business associate arrangement.

A. **Required Elements.**

All business associate agreements (or amendments) must contain the following elements are specified in the Privacy Rule:

1. Describe the permitted and required uses of PHI by the business associate;

2. Provide that the business associate will not use or further disclose the PHI other than as permitted or required by the contract or as required by law;

3. Require that the business associate use appropriate safeguards to prevent a use or disclosure of the PHI other than as provided for by the business associate agreement;

4. Require that the business associate use reasonable administrative, technical and physical safeguards to protect electronic PHI;

5. Report to UCLA Health any use or disclosure not permitted by the agreement, including any suspected security incidents relating to electronic PHI;
6. Ensure that any agents or subcontractors of the business associate agree to the same restrictions and conditions as the business associate;

7. Make available to UCLA Health the information necessary for UCLA Health to comply with its patients’ rights to have access to their PHI, and to request amendments and receive an accounting of disclosures of their PHI (See: Privacy Policy and Procedure Nos. 9413, “Patient Requests To Access and Receive Copies of Protected Health Information (“PHI”) in Any Format, Including Electronic" Patient Access to Protected Health Information (PHI),” No. 9415, “Requests for Amendment of Protected Health Information (PHI),” and 9416 “Requests for Accounting of Disclosures”);

8. Make available to the Secretary of the Department of Health and Human Services (“DHHS”) the business associate’s internal practices, books and records relating to the use and disclosure of the PHI; and

9. Return or destroy the information once the contract expires or is terminated earlier, if feasible.

B. Required Form Agreement (or Amendment).

UCLA Health must use the University of California-approved Business Associate Agreement (amendment) attached as Appendix E effective April 20, 2005 for all new Business Associates.

A Security Amendment, attached as Appendix D, will be utilized effective April 20, 2005 for Business Associates that executed Business Associate Agreements under the Privacy Regulations and who also maintain, create, transmit or receive PHI in an electronic format.

The Business Associate Agreement (amendment) executed under the Privacy Regulations will remain in effect for Business Associates who do not maintain, create, transmit or receive PHI in an electronic format (Attached as Appendix C). (Form No. 1 must be used when UCLA Health has or plans to enter into an agreement with a business associate. Form No. 2 must be used when UCLA Health is acting as a business associate for another entity (also referred to as the “reverse form”).

C. Governmental Entities.

When UCLA Health has a business associate relationship with an entity
that is also a governmental entity, the requirements of the business associate amendment may be met by:

1. Entering into a Memorandum of Understanding (MOU) with the governmental entity; or

2. Determining if current state or federal law requires that the governmental entity/business associate comply with regulations that meet the objectives of the Privacy Rule Business Associate Standard.

The University of California Office of the General Counsel will provide UCLA Health with a legal opinion as to whether an MOU is necessary in those situations where UCLA Health has a business associate relationship with another governmental entity. The UCLA Health Chief Privacy Officer will document those determinations.

V. Breach and Termination

A. UCLA Health is not liable for the privacy and security violations of a business associate, nor does it need to actively monitor or oversee the business associate compliance. The business associate is obligated to notify UCLA Health of a violation.

B. If UCLA Health knows of a pattern of activity or practice of the business associate that is a material breach or violation of the business associate’s obligation under the agreement, UCLA Health must take “reasonable steps” to cure the breach or end the violation. If these measures are unsuccessful, then UCLA Health must terminate the agreement, if feasible, or, if termination is not feasible, report the problem to the Secretary of DHHS.

VI. Data Aggregation Services

While business associates are generally prohibited from uses or disclosures of PHI that would be prohibited if done by UCLA Health, an exception exists for business associates providing data aggregation services related to a covered entity’s operations. “Data aggregation” means the combining by a business associate of PHI received or created as a business associate of one covered entity with PHI received as a business associate of another covered entity, to permit data analyses relating to the health care operations of the respective covered entities.
PROCEDURE

I. The authority to execute agreements has been delegated from the University's Office of the President and/or the Office of the Chancellor to certain individuals on the UCLA campus ("Authorized Employees"). Only those Authorized Employees who have been granted or delegated the authority to execute such an agreement may negotiate and execute a Business Associate Amendment necessary for the agreement.

II. Each Authorized Employee shall be responsible for determining whether a Business Associate relationship exists between UCLA and an outside entity. The "Decision Tree for Determining BAA Relationship" (Appendix B) is to be completed and included in the applicable Purchase Office or related vendor contract file.

If it is determined that a Business Associate relationship does exist, the Authorized Employee shall be responsible for reviewing, negotiating and executing a Business Associate Amendment using the University's standard form Amendment. The Chief Privacy Officer, upon consultation with University legal counsel, must approve any modifications to the University’s standard form.

III. Questions regarding whether a Business Associate relationship exists should be referred to the Chief Privacy Officer and/or University legal counsel.

REFERENCES

Health Insurance Portability and Accountability Act, 45 CFR 160-164
California Medical Information Act, California Civil Code Section 56 et seq.
Information Practices Act of 1977, California Civil Code Sections 1798.29 and 1798.82
California Health and Safety Code Sections 1280.15 and 130203
University of California – HIPAA Business Associates Policy

CONTACT

Chief Privacy Officer, Compliance Office
Chief Information Security Officer, Compliance Office

REVISION HISTORY

Approved: April 8, 2003; February 22, 2006
Effective Date: April 14, 2003; April 20, 2005
APPROVAL
Health Sciences Enterprise Compliance Oversight Board
Approved 12/11/2010

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Health Insurance Portability and Accountability Act, 45 CFR 160-164
California Medical Information Act, California Civil Code Section 56 et seq.

REVISION HISTORY
Approved: April 8, 2003; February 22, 2006
Effective Date: April 14, 2003; April 20, 2005

APPROVAL

Compliance Committee

Chief Compliance Officer
APPENDIX A

EXAMPLES OF BUSINESS ASSOCIATE RELATIONSHIPS

Examples of business associate relationships include:

* Contracts with billing companies for claims processing services. Because the billing company is acting on behalf of the provider and is receiving PHI in the form of patient billing information, the billing company is a business associate.

* Contracts with a vendor to outsource certain information technology services, such as claims processing and data warehousing.

* Contracts with software companies that host the software containing PHI on its own server or accesses PHI when troubleshooting the software function, except when the employee of an outside vendor has his or her primary duty station onsite at UCLA Health System, then UCLA Health System may choose to treat the employee as a Workforce member, rather than as a business associate.

* Contracts with independent consultants to review the accuracy of billing and coding practices.

* Contracts with outside counsel or consultants whose services involve access to PHI.

* Contracts with a service that provides routine handling of records or shredding of documents containing PHI (as different from a janitorial service) unless the work is under the direct control of UCLA Health System, when it can be considered a part of the Workforce.

* Contracts with health plans in which UCLA Health System has been delegated to provide certain services (e.g. credentialing, utilization management) on behalf of the health plan.

Examples that are not business associate relationships include:

* UCLA Health System allows staff in its billing office to use PHI to generate claims for payment. They are members of the UCLA Health System Workforce and are not business associates.

* A member of a hospital’s medical staff has access to health records to treat patients. The physician is not the hospital’s business associate, because he or she is not performing an activity on behalf of the hospital.
UCLA Health System uses a courier service to deliver medical records to a laboratory. The courier service is not a business associate of UCLA Health System, even if it has occasional access to PHI.

Incidental disclosures to individuals or entities that could not be reasonably prevented and occurs as by-product of their duties (e.g., janitorial or electrician services, photocopy repair technicians);

PHI disclosed to researchers for research purposes (see: Privacy Policy and Procedure No. 400, “Privacy Requirements Relating to Research”).

Contracts with health plans in which UCLA Health System has not been delegated to provide certain services (e.g. credentialing, utilization management) on behalf of the health plan.
APPENDIX B

Decision Tree for Determining BAA Relationship

Contact is:
1. If the Business Associate requests any changes to the terms of the BAA agreement, forward the agreement to the Privacy Officer for review.
2. If the Business Associate agrees to the terms of the standard UIC agreement, forward one of the signed originals to the Purchasing Director and return one signed original to the Business Associate.

What type of contract is this?

Type:
- Maintenance (Maint) / (Service) / (Lease) / (LR-Lease Renewal or Revision) / (CAP-Capital Asset) / (Blanket Purchase Order-BPO)
  - e.g., copiers, scanners, phones, beds, etc.

- Lease
- Maintenance / Service

Does this machine store PHI?

YES

Does vendor have access to PHI during maintenance?

YES

No BAA needed

"Reminder: Vendor on-site must follow process for confidentiality outlined in policy UCLA Vendor Policy.

is there the possibility of disclosure of PHI: ______ normal

NO

NO BAA needed

LEGEND

FDA - Business Associate
BAA - Business Associate Addendum of Business Associate Agreement
HIPAA - Health Insurance Portability and Accountability Act
PHI - Patient Health Information

POLICIES REFERENCED
Available on UCLA Internet http://mednet.ucla.edu
HIPAA Business Associate Agreement Policy, UCLA Contract Authority,
UCLA Expenditure Approval Authority, UCLA Vendor Representative Policy

To be completed by person conducting analysis:

VENDOR NAME: ____________________
SIGNATURE: ____________________
DATE: ____________________
PURCHASE ORDER #: ____________________

NOTE: Track your progress through the decision tree by placing a check mark in the circle.
APPENDIX C

FORM 1
(TO BE USED WITH UCLA HEALTH SYSTEM’S BUSINESS ASSOCIATES)

HIPAA BUSINESS ASSOCIATE AMENDMENT

This HIPAA Business Associate Amendment ("Amendment") supplements and is made a part of the Agreement ("Agreement") by and between The Regents of the University of California on behalf of UCLA Health System ("UCLA") and ________________________ ("BUSINESS ASSOCIATE") and is effective as of April 14, 2003 (the "Amendment Effective Date").

RECITALS

A. UCLA and BUSINESS ASSOCIATE desire to protect the privacy and provide for the security of Protected Health Information used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996, ("HIPAA") and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the "HIPAA Regulations") and other applicable laws and regulations.

B. UCLA, pursuant to the terms of the Agreement, wishes to disclose to BUSINESS ASSOCIATE certain information, some of which may constitute Protected Health Information.

C. BUSINESS ASSOCIATE provides services, arranges, performs or assists in the performance or activities of UCLA and uses or discloses Protected Health Information pursuant to the HIPAA Regulations, 45 CFR Section 160.103.

D. “Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 164.501. The purpose of this Amendment is to satisfy certain standards and requirements of HIPAA and the HIPAA Regulations, including, but not limited to, Title 45, Section 164.504(e) of the Code of Federal Regulations ("CFR"), as the same may be amended from time to time.
In consideration of the mutual promises made below and the exchange of information pursuant to the Agreement, amendments to the Agreement (herein collectively the “Agreement”) and this Amendment, the parties agree as follows:

1. **Responsibilities of BUSINESS ASSOCIATE.**

   a. **Permitted Uses and Disclosures.** BUSINESS ASSOCIATE may use and/or disclose PHI received by BUSINESS ASSOCIATE pursuant to the Agreement and this Amendment solely for the purpose of performing its obligations under the Agreement and this Amendment.

   b. **Restrictions of PHI.** BUSINESS ASSOCIATE shall notify UCLA in writing within two (2) working days of receipt of any request by patients or their representatives to restrict the use and disclosure of the PHI BUSINESS ASSOCIATE maintains for or on behalf of UCLA. Upon written notice from UCLA, BUSINESS ASSOCIATE agrees to comply with any instructions to modify, delete or otherwise restrict the use and disclosure of PHI it maintains for or on behalf of UCLA.

   c. **Disclosure of PHI.** BUSINESS ASSOCIATE may, if necessary, use PHI (i) for the proper management and administration of BUSINESS ASSOCIATE’s business or (ii) to carry out BUSINESS ASSOCIATE’s legal responsibilities.

   d. **Data Aggregation Services.** If applicable, and as requested by UCLA, BUSINESS ASSOCIATE shall provide data aggregation services related to the health care operations of UCLA.

   e. **Nondisclosure.** BUSINESS ASSOCIATE is not authorized and shall not use or further disclose UCLA’s PHI other than as permitted under the Agreement or this Amendment, or as required by law or regulation.

   f. **Safeguards.** BUSINESS ASSOCIATE shall use appropriate administrative, technical and physical safeguards to prevent any use or disclosure of UCLA’s PHI other than as provided for by the Agreement and this Amendment.

   g. **Reporting of Disclosures.** BUSINESS ASSOCIATE shall notify UCLA in writing within two (2) working days of its discovery of any use or disclosure of UCLA’s PHI not permitted by the Agreement or this Amendment of which BUSINESS ASSOCIATE or its officers, employees or agents become aware. BUSINESS ASSOCIATE shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.
h. **Compliance with Law.** BUSINESS ASSOCIATE shall comply with all applicable federal and state laws and regulations, including the HIPAA Standards for Electronic Transactions, 45 CFR Parts 160 and 162, if applicable under the terms and requirements of this Agreement.

i. **BUSINESS ASSOCIATE’s Agents.** BUSINESS ASSOCIATE shall ensure that any agent or subcontractor agrees with BUSINESS ASSOCIATE in writing that the agent or subcontractor will hold the PHI confidentially and use or disclose the PHI only as required by law or for the purpose it was used or disclosed to the agent or subcontractor. Additionally, the agent or subcontractor shall notify BUSINESS ASSOCIATE of any instances of which it is aware in which the confidentiality of the PHI has been breached.

j. **Availability and Accounting of Information.** BUSINESS ASSOCIATE shall, within ten (10) working days of receipt of a written request, make available to UCLA and, if authorized in writing by UCLA, to the subject of the PHI, such information as may be required to fulfill UCLA’s obligations to provide access to, provide a copy of, and account for disclosures of UCLA’s PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Sections 164.524 and 164.528. The accounting shall include: i) the date of the disclosure, ii) the name and address of the entity or person who received the PHI, iii) a brief description of the PHI disclosed, and iv) a brief statement of the basis for the disclosure or a copy of an authorization for the disclosure.

k. **Amendment of PHI.** BUSINESS ASSOCIATE shall inform UCLA within two (2) working days of receipt of any request by or on behalf of the subject of the PHI to amend the PHI that BUSINESS ASSOCIATE maintains for or on behalf of UCLA. BUSINESS ASSOCIATE shall, within ten (10) working days of receipt of a written request, make the subject’s PHI available to UCLA as may be required to fulfill UCLA’s obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 164.526. BUSINESS ASSOCIATE shall, as directed by UCLA, incorporate any amendments to UCLA’s PHI into copies of such PHI maintained by BUSINESS ASSOCIATE.

l. **Regulatory Compliance.** BUSINESS ASSOCIATE shall make its internal practices, books and records relating to the use and disclosure of PHI received from UCLA (or created or received by BUSINESS ASSOCIATE on behalf of UCLA) available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining UCLA’s compliance with the HIPAA Regulations.

m. **Inspection of Records.** Within thirty (30) calendar days of a written request, BUSINESS ASSOCIATE shall make available to UCLA during normal business hours.
hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of UCLA’s PHI for purposes of enabling UCLA to determine BUSINESS ASSOCIATE’s compliance with the terms of this Amendment.

n. Certification. UCLA and its authorized agents or contractors, may examine BUSINESS ASSOCIATE’s facilities, systems, procedures, and records as may be necessary to determine the extent to which BUSINESS ASSOCIATE’s security safeguards comply with HIPAA, the HIPAA Regulations, or this Amendment.

2. Termination.

a. Material Breach. A breach by BUSINESS ASSOCIATE of any material provision of this Amendment, as determined by UCLA, shall constitute a material breach of the Agreement, and shall provide grounds for immediate termination of the Agreement by UCLA.

b. Effect of Termination. Upon termination of the Agreement for any reason, BUSINESS ASSOCIATE shall return or, at the option of UCLA, destroy all PHI received from UCLA, or created and received by BUSINESS ASSOCIATE on behalf of UCLA, that BUSINESS ASSOCIATE still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, BUSINESS ASSOCIATE shall continue to extend indefinitely the protections of this Amendment to such information, and immediately terminate any further use or disclosure of such PHI.

3. Changes to the Amendment.

a. Compliance with Law. The parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that changes to this Amendment may be required to ensure compliance with such developments. The parties specifically agree to take such action as may be necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations and other applicable state and federal laws relating to the security or confidentiality of PHI.

b. Negotiations. In the event of a change in or interpretation of any state or federal law, statute, or regulation which materially affects the rights or obligations of either party under the Agreement or this Amendment, the parties agree to negotiate immediately in good faith any necessary or appropriate revisions to the Agreement. If the parties are unable to reach an agreement concerning such revisions within the earlier of sixty (60) calendar days after the date of notice seeking negotiations or the effective date of a change in law or regulation, then either party may immediately terminate this Agreement upon written notice to the other.
4. **Indemnification.**

   a. **Indemnification by BUSINESS ASSOCIATE.** BUSINESS ASSOCIATE agrees to defend at UCLA’s election, indemnify, and hold harmless UCLA, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys' fees) or claims for injury or damages that are caused by or result from the acts or omissions of BUSINESS ASSOCIATE, its officers, agents or employees with respect to the use and disclosure of UCLA’s PHI.

   b. **Indemnification by UCLA.** UCLA agrees to defend at BUSINESS ASSOCIATE’s election, indemnify, and hold harmless BUSINESS ASSOCIATE, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys' fees) or claims for injury or damages that are caused by or result from the acts or omissions of UCLA, its officers, agents or employees with respect to the use and disclosure of UCLA’s PHI.

5. **Miscellaneous Provisions.**

   a. **No Third Party Beneficiaries.** Nothing express or implied in this Amendment is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than UCLA, BUSINESS ASSOCIATE and their respective successors or assigns.

   b. **Notice to Secretary.** If UCLA knows of a pattern of activity or practice of BUSINESS ASSOCIATE that constitutes a material breach or violation of BUSINESS ASSOCIATE'S obligation under this Amendment, if the breach or violation continues, and if termination of this Amendment is not feasible, UCLA is required by the HIPAA regulations to report the problem to the Secretary of Health and Human Services.

   c. **Survival.** The obligations of BUSINESS ASSOCIATE under Sections 1(j), 1(l), 1(m), 2(b), 4(a), 4(b) and 5(a) of this Amendment shall survive the termination of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment to the Agreement.

The Regents of the University of California _______________________
On behalf of UCLA Health System (“UCLA”) _______________________

___________________________________  _________________________
___________________________________  _________________________

("BUSINESS ASSOCIATE")
HIPAA BUSINESS ASSOCIATE AMENDMENT

This HIPAA Business Associate Amendment ("Amendment") supplements and is made a part of the Agreement ("Agreement") by and between The Regents of the University of California on behalf of UCLA Health System ("BUSINESS ASSOCIATE") and ____________________________________ ("COMPANY") and is effective as of April 14, 2003 (the "Amendment Effective Date").

RECITALS

A. COMPANY and BUSINESS ASSOCIATE desire to protect the privacy and provide for the security of Protected Health Information used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996, ("HIPAA") and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable laws and regulations.

B. COMPANY, pursuant to the terms of the Agreement, wishes to disclose to BUSINESS ASSOCIATE certain information, some of which may constitute Protected Health Information.

C. BUSINESS ASSOCIATE provides services, arranges, performs or assists in the performance or activities of COMPANY and uses or discloses PHI, pursuant to the HIPAA Regulations, 45 CFR Section 160.103.

D. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 164.501. The purpose of this Amendment is to satisfy certain standards and requirements of HIPAA and the HIPAA Regulations, including, but not limited to, Title 45, Section 164.504(e) of the Code of Federal Regulations ("CFR"), as the same may be amended from time to time.
In consideration of the mutual promises made below and the exchange of information pursuant to the Agreement, amendments to the Agreement (herein collectively the “Agreement”) and this Amendment, the parties agree as follows:

1. Responsibilities of BUSINESS ASSOCIATE.

   a. Permitted Uses and Disclosures. BUSINESS ASSOCIATE may use and/or disclose PHI received by BUSINESS ASSOCIATE pursuant to the Agreement and this Amendment solely for the purpose of performing its obligations under the Agreement and this Amendment.

   b. Restrictions of PHI. BUSINESS ASSOCIATE shall notify COMPANY in writing within five (5) working days of receipt of any request by patients or their representatives to restrict the use and disclosure of the PHI BUSINESS ASSOCIATE maintains for or on behalf of COMPANY. Upon written notice from COMPANY, BUSINESS ASSOCIATE agrees to comply with any instructions to modify, delete or otherwise restrict the use and disclosure of PHI it maintains for or on behalf of COMPANY.

   c. Disclosure of PHI. BUSINESS ASSOCIATE may, if necessary, use PHI (i) for the proper management and administration of BUSINESS ASSOCIATE’s business or (ii) to carry out BUSINESS ASSOCIATE’s legal responsibilities.

   d. Nondisclosure. BUSINESS ASSOCIATE is not authorized and shall not use or further disclose COMPANY’s PHI other than as permitted under the Agreement or this Amendment, or as required by law or regulation.

   e. Safeguards. BUSINESS ASSOCIATE shall use appropriate administrative, technical and physical safeguards to prevent any use or disclosure of COMPANY’s PHI other than as provided for by the Agreement and this Amendment.

   f. Reporting of Disclosures. BUSINESS ASSOCIATE shall notify COMPANY in writing within five (5) working days of its discovery of any use or disclosure of COMPANY’s PHI not permitted by the Agreement or this Amendment of which BUSINESS ASSOCIATE or its officers, employees or agents become aware. BUSINESS ASSOCIATE shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.

   g. Compliance with Law. BUSINESS ASSOCIATE shall comply with all applicable federal and state laws and regulations, including the HIPAA Standards for Electronic Transactions, 45 CFR Parts 160 and 162, if applicable under the terms and requirements of this Agreement.
h. **BUSINESS ASSOCIATE’s Agents.** BUSINESS ASSOCIATE shall ensure that any agent or subcontractor agrees with BUSINESS ASSOCIATE in writing that the agent or subcontractor will hold the PHI confidentially and use or disclose the PHI only as required by law or for the purpose it was used or disclosed to the agent or subcontractor. Additionally, the agent or subcontractor shall notify BUSINESS ASSOCIATE of any instances of which it is aware in which the confidentiality of the PHI has been breached.

i. **Availability and Accounting of Information.** BUSINESS ASSOCIATE shall, within twenty (20) calendar days of receipt of a written request, make available to COMPANY and, if authorized in writing by COMPANY, to the subject of the PHI, such information as may be required to fulfill COMPANY’s obligations to provide access to, provide a copy of, and account for disclosures of COMPANY’s PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Sections 164.524 and 164.528. The accounting shall include: i) the date of the disclosure, ii) the name and address of the entity or person who received the PHI, iii) a brief description of the PHI disclosed, and iv) a brief statement of the basis for the disclosure or a copy of an authorization for the disclosure.

j. **Amendment of PHI.** BUSINESS ASSOCIATE shall inform COMPANY within five (5) working days of receipt of any request by or on behalf of the subject of the PHI to amend the PHI BUSINESS ASSOCIATE maintains for or on behalf of COMPANY. BUSINESS ASSOCIATE shall, within twenty (20) calendar days of receipt of a written request, make the subject’s PHI available to COMPANY as may be required to fulfill COMPANY’s obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 164.526. BUSINESS ASSOCIATE shall, as directed by COMPANY, incorporate any amendments to COMPANY’s PHI into copies of such PHI maintained by BUSINESS ASSOCIATE.

k. **Regulatory Compliance.** BUSINESS ASSOCIATE shall make its internal practices, books and records relating to the use and disclosure of PHI received from COMPANY (or created or received by BUSINESS ASSOCIATE on behalf of COMPANY) available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining COMPANY’s compliance with the HIPAA Regulations.

l. **Inspection of Records.** Within thirty (30) calendar days of a written request, BUSINESS ASSOCIATE shall make available to COMPANY during normal business hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of COMPANY’s PHI for purposes of enabling COMPANY to determine BUSINESS ASSOCIATE’s compliance with the terms of this Amendment.
m. **Certification.** COMPANY and its authorized agents or contractors, may examine BUSINESS ASSOCIATE’s facilities, systems, procedures, and records as may be necessary to determine the extent to which BUSINESS ASSOCIATE’s security safeguards comply with HIPAA, the HIPAA Regulations, or this Amendment.

2. **Termination.**

   a. **Material Breach.** A breach by BUSINESS ASSOCIATE of any material provision of this Amendment, as determined by COMPANY, shall constitute a material breach of the Agreement, and shall provide grounds for immediate termination of the Agreement by COMPANY.

   b. **Effect of Termination.** Upon termination of the Agreement for any reason, BUSINESS ASSOCIATE shall return or, at the option of COMPANY, destroy all PHI received from COMPANY, or created and received by BUSINESS ASSOCIATE on behalf of COMPANY, that BUSINESS ASSOCIATE still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, BUSINESS ASSOCIATE shall continue to extend indefinitely the protections of this Amendment to such information, and immediately terminate any further use or disclosure of such PHI.

3. **Changes to the Amendment.**

   a. **Compliance with Law.** The parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that changes to this Amendment may be required to ensure compliance with such developments. The parties specifically agree to take such action as may be necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations and other applicable state and federal laws relating to the security or confidentiality of PHI.

   b. **Negotiations.** In the event of a change in or interpretation of any state or federal law, statute, or regulation which materially affects the rights or obligations of either party under the Agreement or this Amendment, the parties agree to negotiate immediately in good faith any necessary or appropriate revisions to the Agreement. If the parties are unable to reach an agreement concerning such revisions within the earlier of sixty (60) calendar days after the date of notice seeking negotiations or the effective date of a change in law or regulation, then either party may immediately terminate this Agreement upon written notice to the other.
4. **Indemnification.**

c. **Indemnification by BUSINESS ASSOCIATE.** BUSINESS ASSOCIATE agrees to defend at COMPANY’s election, indemnify, and hold harmless COMPANY, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys' fees) or claims for injury or damages that are caused by or result from the acts or omissions of BUSINESS ASSOCIATE, its officers, agents or employees with respect to the use and disclosure of COMPANY’s PHI.

d. **Indemnification by COMPANY.** COMPANY agrees to defend at BUSINESS ASSOCIATE’s election, indemnify, and hold harmless BUSINESS ASSOCIATE, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys' fees) or claims for injury or damages that are caused by or result from the acts or omissions of COMPANY, its officers, agents or employees with respect to the use and disclosure of COMPANY’s PHI.

5. **Miscellaneous Provisions.**

a. **No Third Party Beneficiaries.** Nothing express or implied in this Amendment is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than COMPANY, BUSINESS ASSOCIATE, and their respective successors or assigns.

b. **Notice to Secretary.** If COMPANY knows of a pattern of activity or practice of BUSINESS ASSOCIATE that constitutes a material breach or violation of BUSINESS ASSOCIATE’S obligation under this Amendment, if the breach or violation continues, and if termination of this Amendment is not feasible, COMPANY is required by the HIPAA regulations to report the problem to the Secretary of Health and Human Services.

c. **Survival.** The obligations of BUSINESS ASSOCIATE under Sections 1(k), 1(l), 2(b), 4(a), 4(b) and 5(a) of this Amendment shall survive the termination of this Agreement.
IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment to the Agreement.

The Regents of the University of California
On behalf of UCLA Health System
(“BUSINESS ASSOCIATE”)

[NAME OF COMPANY]
(“COMPANY”)

___________________________________   _________________________
___________________________________   _________________________
Appendix D
Security Amendment to Existing Business Associates who handle ePHI

HIPAA BUSINESS ASSOCIATE AMENDMENT – FIRST AMENDMENT (SECURITY)

This First Amendment supplements and is made part of the HIPAA Business Associate Amendment ("BA Amendment") by and between The Regents of the University of California on behalf of the University of California Los Angeles Healthcare ("UCLA") and ______________ ("BUSINESS ASSOCIATE") and is effective as of April 20, 2005.

RECITAL

UCLA and BUSINESS ASSOCIATE have executed the BA Amendment in order to protect the privacy and provide for the security of Protected Health Information used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996, ("HIPAA") and regulations promulgated there under by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable laws and regulations, including, but not limited to 45 Code of Federal Regulations ("CFR"), Section 164.504(e), as the same may be amended from time to time. Pursuant to Section 3.a. of the BA Amendment, the purpose of this First Amendment is to supplement the BA Amendment to comport with the final HIPAA Privacy and Security regulations. Accordingly, the BA Amendment is amended as follows:

A. Paragraph D. of the BA Amendment Recitals is deleted in its entirety and replaced with the following:

D. "Protected Health Information" or "PHI" means any information, including Electronic PHI, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103.

B. Paragraph “E” of the Recitals is re-numbered as paragraph “H”.

C. The following paragraphs E., F. and G. are added to the BA Amendment Recitals after paragraph D., as follows:

E. “Electronic PHI” means PHI that is transmitted by or maintained in electronic media and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103.

F. “Security Incident” means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 164.304.

G. “Information System” means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications,
communications, and people, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 164.304.

D. Section 1, “Responsibilities of BUSINESS ASSOCIATE” is amended as follows:

1. Subsection (e), “Safeguards,” is deleted in its entirety and replaced with the following:

   e. **Safeguards.** BUSINESS ASSOCIATE shall develop, implement, maintain and use commercially acceptable administrative, technical and physical security measures to preserve the confidentiality, integrity and availability of all the UCLA’s PHI and Electronic PHI that it creates, receives, maintains, or transmits on behalf of UCLA.

2. Subsection (f), “Reporting of Disclosures,” is deleted in its entirety and replaced with the following:

   f. **Reporting of Disclosures.**

   1. BUSINESS ASSOCIATE shall:

      a. Notify UCLA in writing within two (2) business days of its discovery of a Security Incident or of any use or disclosure of UCLA’s PHI not permitted by this BA Amendment of which BUSINESS ASSOCIATE or its officers, employees, agents and subcontractors become aware;

      b. Take prompt corrective action to cure any deficiencies;

      c. Take action pertaining to such Security Incident or unauthorized use or disclosure as required by applicable federal and state laws and regulations;

      d. Provide, within twenty (20) days of the notification described in f.1.a. above, written notice to UCLA of: (i) the actions taken by the BUSINESS ASSOCIATE to mitigate any harmful effect of the Security Incident or of the unauthorized use or disclosure and (ii) what corrective action the BUSINESS ASSOCIATE has taken or shall take to prevent any future Security Incident or unauthorized use or disclosure.

2. If UCLA determines that the written notice from BUSINESS ASSOCIATE does not provide sufficient assurances regarding the actions taken by BUSINESS ASSOCIATE, then within fifteen (15) business days following UCLA’s request, BUSINESS ASSOCIATE shall provide an audit or accounting of all Security Incidents and uses and disclosures of UCLA’s PHI that is or has been maintained, used, or disclosed by BUSINESS ASSOCIATE or its agents or subcontractors.

3. If the accounting is not provided in a timely manner or UCLA is not satisfied that the corrective action is sufficient to reasonably prevent similar future occurrences, UCLA may terminate the Agreement.

3. Subsection (g), “Compliance with Law,” is amended by deleting the words “and 162”, and adding in their place the words “, 162 and 164.”
4. Subsection (h), “BUSINESS ASSOCIATE’s AGENTS,” is deleted in its entirety and replaced with the following:

   h. BUSINESS ASSOCIATE’s Agents or Subcontractors. BUSINESS ASSOCIATE may provide UCLA’s PHI only to agents or subcontractors approved in advance by UCLA and solely for the purposes of carrying out the Agreement. In compliance with 45 CFR Sections 164.314 and 164.504, BUSINESS ASSOCIATE certifies that any agent, including a subcontractor, of the BUSINESS ASSOCIATE to whom BUSINESS ASSOCIATE provides UCLA’s PHI, including Electronic PHI, as permitted under this BA Amendment, shall have a written agreement with BUSINESS ASSOCIATE that the agent or subcontractor shall agree to the same restrictions and conditions that apply to BUSINESS ASSOCIATE with respect to UCLA’s PHI, implement reasonable and appropriate administrative, physical, and technical safeguards and restrictions to protect the confidentiality, integrity and availability of UCLA’s PHI, and use or disclose the PHI only as required by law or for the purpose it was used or disclosed. Additionally, the agent or subcontractor shall promptly notify BUSINESS ASSOCIATE and UCLA of any Security Incident or of any use or disclosure of PHI not permitted under this BA Amendment of which the agent or subcontractor becomes aware. BUSINESS ASSOCIATE shall notify UCLA within five (5) days of this Security Incident or unauthorized use or disclosure. Following such notice and upon the request of UCLA, BUSINESS ASSOCIATE shall provide within fifteen (15) days an audit or written accounting of all BUSINESS ASSOCIATE’s or BUSINESS ASSOCIATE’s agent’s, including subcontractor’s, uses and disclosures of UCLA’s PHI.

5. A new subsection (n), “Workforce Training,” is added at the end of Section 1, as follows:

   n. Workforce Training. BUSINESS ASSOCIATE certifies that all members of BUSINESS ASSOCIATE’s workforce who are using or disclosing UCLA’s PHI under this BA Amendment have been trained on BUSINESS ASSOCIATES’ policies and practices, developed in compliance with HIPAA Privacy Rules.

IN WITNESS WHEREOF, the parties hereto have duly executed this First Amendment to the BA Amendment.

The Regents of the University of California
On behalf of its University of California Health System

[Name of BUSINESS ASSOCIATE]

Signature
Printed Name
Title
Date
APPENDIX E
To be utilized for all new Business Associates effective April 20, 2005

HIPAA BUSINESS ASSOCIATE AMENDMENT

This HIPAA Business Associate Amendment ("Amendment") supplements and is made a part of the Agreement ("Agreement") by and between The Regents of the University of California on behalf of UCLA Health System ("UCLA") and ___________ ("BUSINESS ASSOCIATE") and is effective as of ________________ [Enter the date the effective date of the underlying agreement].

RECITALS

A. UCLA and BUSINESS ASSOCIATE desire to protect the privacy and provide for the security of Protected Health Information used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996, ("HIPAA") and regulations promulgated there under by the U.S. Department of Health and Human Services (45 CFR Parts 160, 162 and 164, the "HIPAA Regulations") and other applicable laws and regulations. The purpose of this Amendment is to satisfy certain standards and requirements of HIPAA and the HIPAA Regulations, including 45 CFR Section 164.504(e) as it may be amended from time to time.

B. UCLA, pursuant to the terms of the Agreement, wishes to disclose to BUSINESS ASSOCIATE certain information, some of which may constitute Protected Health Information.

C. BUSINESS ASSOCIATE provides services, arranges, performs or assists in the performance or activities of UCLA and uses or discloses Protected Health Information pursuant to the HIPAA Regulations, 45 CFR Section 160.103.

D. "Protected Health Information" or "PHI" means any information, including Electronic PHI, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103.

E. “Electronic PHI” means PHI that is transmitted by or maintained in electronic media and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 160.103.

F. “Security Incident” means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 164.304.

G. "Information System" means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 164.304.

H. In consideration of the mutual promises made below and the exchange of information pursuant to the Agreement, amendments to the Agreement (herein collectively the “Agreement”) and this Amendment, the parties agree as follows:
1. **Responsibilities of BUSINESS ASSOCIATE.**
   
a. **Permitted Uses and Disclosures.** BUSINESS ASSOCIATE may use and/or disclose PHI received by BUSINESS ASSOCIATE pursuant to the Agreement and this Amendment solely for the purpose of performing its obligations under the Agreement and this Amendment.

b. **Disclosure of PHI.** BUSINESS ASSOCIATE may, if necessary, use PHI (i) for the proper management and administration of BUSINESS ASSOCIATE’s business or (ii) to carry out BUSINESS ASSOCIATE’s legal responsibilities.

c. **Nondisclosure of PHI.** BUSINESS ASSOCIATE is not authorized and shall not use or further disclose UCLA’s PHI other than as permitted under the Agreement or this Amendment, or as required by law or regulation.

d. **Safeguards.** BUSINESS ASSOCIATE shall use appropriate administrative, technical and physical safeguards to protect the confidentiality, integrity and availability of UCLA’s Electronic PHI and to prevent any use or disclosure of UCLA’s PHI other than as provided for by the Agreement and this Amendment. BUSINESS ASSOCIATE certifies that it will protect UCLA’s PHI and information received from or created on behalf of UCLA according to commercially acceptable standards and no less rigorously than it protects its own confidential information.

e. **Workforce Training.** BUSINESS ASSOCIATE certifies that all members of BUSINESS ASSOCIATE’S workforce who are using or disclosing UCLA’s PHI on behalf of UCLA have been trained on BUSINESS ASSOCIATE’S policies and practices regarding compliance with the requirements of the HIPAA Privacy and Security Rules.

f. **Reporting Actual or Suspected Disclosures Not Permitted By This Amendment.**
   
   1. **Notification.** BUSINESS ASSOCIATE shall notify UCLA in writing within two (2) days of its discovery of any Security Incident or of any actual or suspected use or disclosure of UCLA’s PHI not permitted by this Amendment of which BUSINESS ASSOCIATE or its officers, employees or agents become aware. BUSINESS ASSOCIATE shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.

   2. **Right of UCLA to Accounting or Audit.** If UCLA receives information from BUSINESS ASSOCIATE or from other sources that there has been a breach or suspected breach of this Amendment that could result in use or disclosure of UCLA’s PHI that is not permitted by this Amendment, BUSINESS ASSOCIATE shall provide, upon UCLA’s request and at BUSINESS ASSOCIATE’S expense, an audit or written accounting of all BUSINESS ASSOCIATE’s uses and disclosures of UCLA’s PHI.

   3. **Written Notification of Corrective Action Taken and Provision of Policies.** BUSINESS ASSOCIATE will provide written notice to UCLA within twenty (20) days of the discovery of any use or disclosure of UCLA’s PHI not permitted by this Amendment, including: (i) the actions taken by BUSINESS ASSOCIATE to mitigate any harmful effect of the unauthorized use or disclosures and (ii) what corrective action BUSINESS ASSOCIATE has taken or shall take to prevent future similar unauthorized use or disclosure. Upon request, BUSINESS ASSOCIATE will also provide to UCLA a copy of BUSINESS ASSOCIATE’s policies and procedures that address the use and disclosure of UCLA’s PHI and procedures for curing any material breach of this Amendment.
4. **Accounting or Audit of BUSINESS ASSOCIATE’S USES OF PHI.** If UCLA determines that the written notice does not provide sufficient assurances that the breach has been cured, then within fifteen (15) days following UCLA’s request, BUSINESS ASSOCIATE shall provide an audit or accounting of all uses and disclosures of UCLA’s PHI maintained, used or disclosed by BUSINESS ASSOCIATE or by BUSINESS ASSOCIATE’S agents.

5. If BUSINESS ASSOCIATE fails to provide the accounting or audit in a timely manner, or if UCLA is not satisfied that the corrective action is sufficient to reasonably prevent similar occurrences in the future, UCLA may terminate the Agreement in accordance with Section 2.

g. **BUSINESS ASSOCIATE’s Agents.**

With respect to its Agents, BUSINESS ASSOCIATE acknowledges that this Amendment allows BUSINESS ASSOCIATE to provide UCLA’s PHI only to Agents approved in advance by UCLA and solely for the purposes of carrying out the Agreement. Furthermore, BUSINESS ASSOCIATE shall:

1. Require such Agents to agree to the same restrictions and conditions that are imposed on BUSINESS ASSOCIATE by this Amendment, and to provide written assurance to BUSINESS ASSOCIATE that the Safeguard section (1.d.) and Workforce Training (1.e) section have been met.

2. Ensure that such Agents agree with BUSINESS ASSOCIATE in writing to implement reasonable and appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity and availability of UCLA’s Electronic PHI, hold the PHI confidentially and use or disclose the PHI only as required by law or for the purpose it was used or disclosed to the Agent.

3. Require such Agents to notify BUSINESS ASSOCIATE and UCLA within 2 days of any Security Incident or of any actual or suspected use or disclosure of UCLA’s PHI not permitted by this Amendment of which such Agent or its officers or employees become aware.

4. Provide within twenty (20) business days of the notification in Section g.3 to UCLA written notice of the actions taken by BUSINESS ASSOCIATE to mitigate any harmful effect of the unauthorized use or disclosures by the Agent and what corrective action BUSINESS ASSOCIATE has taken or shall take to prevent any future similar unauthorized use or disclosure.

5. Assure that the Agent has destroyed or returned all UCLA’s PHI to UCLA or BUSINESS ASSOCIATE as required in Section 2.b. upon a material breach or termination of the Agent’s contract with BUSINESS ASSOCIATE. If the Agent maintains that return or destruction is infeasible, BUSINESS ASSOCIATE shall promptly notify UCLA in writing the reason the Agent cannot return or destroy UCLA’s PHI.

6. Be responsible for assuring that the Agent protects the PHI as otherwise required in this Agreement and this Amendment and as required by law.

h. **Individual’s Request for Restrictions of PHI.** BUSINESS ASSOCIATE shall notify UCLA in writing within two (2) business days of receipt of any request by individuals or their representatives to restrict the use and disclosure of the PHI BUSINESS ASSOCIATE maintains
for or on behalf of UCLA. Upon written notice from UCLA that it agrees to comply with the requested restrictions, BUSINESS ASSOCIATE agrees to comply with any instructions to modify, delete or otherwise restrict the use and disclosure of PHI it maintains for or on behalf of UCLA.

i. Individual’s Request for Amendment of PHI. BUSINESS ASSOCIATE shall inform UCLA within two (2) business days of receipt of any request by or on behalf of the subject of the PHI to amend the PHI that BUSINESS ASSOCIATE maintains for or on behalf of UCLA. BUSINESS ASSOCIATE shall, within ten (10) calendar days of receipt of a written request, make the subject’s PHI available to UCLA as may be required to fulfill UCLA’s obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 164.526. BUSINESS ASSOCIATE shall, as directed by UCLA, incorporate any amendments to UCLA’s PHI into copies of such PHI maintained by BUSINESS ASSOCIATE.

j. Individual’s Request for an Accounting of Disclosures of PHI. BUSINESS ASSOCIATE shall, within ten (10) calendar days of receipt of a written request, make available to UCLA, and, if authorized in writing by UCLA, to the subject of the PHI, such information maintained by BUSINESS ASSOCIATE or its agents as may be required to fulfill UCLA’s obligations to provide an accounting for disclosures of UCLA’s PHI pursuant to HIPAA and the HIPAA regulations, including, but not limited to, 45 CFR section 164.528.

k. Access to PHI by the Individual. When UCLA determines that the designated record set is held solely by BUSINESS ASSOCIATE or if BUSINESS ASSOCIATE is acting on behalf of UCLA to provide access to or a copy of the designated record set, BUSINESS ASSOCIATE shall, within two (2) calendar days of receipt of a written request, make available to UCLA, and, if authorized in writing by UCLA, to the subject of the PHI, such information as may be required to fulfill UCLA’s obligations to provide access to or provide a copy of the designated record set of UCLA’s PHI pursuant to HIPAA and the HIPAA regulations, including, but not limited to, 45 CFR sections 164.524.

l. Regulatory Compliance. BUSINESS ASSOCIATE shall make its internal practices, books and records relating to the use and disclosure of PHI received from UCLA (or created or received by BUSINESS ASSOCIATE on behalf of UCLA) available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining UCLA’s compliance with the HIPAA Regulations.

m. Inspection of Records. Within thirty (30) calendar days of a written request, BUSINESS ASSOCIATE shall make available to UCLA during normal business hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of UCLA’s PHI for purposes of enabling UCLA to determine BUSINESS ASSOCIATE’s compliance with the terms of this Amendment.

n. Certification. UCLA and its authorized agents or contractors, may examine BUSINESS ASSOCIATE’s facilities, systems, procedures, and records as may be necessary to determine the extent to which BUSINESS ASSOCIATE’s security safeguards comply with HIPAA, the HIPAA Regulations, or this Amendment.

o. Compliance with Law. BUSINESS ASSOCIATE shall comply with all applicable federal and state laws and regulations, including but not limited to the HIPAA Regulations, 45 CFR Parts 160, 162 and 164.
2. **Termination.**

   a. **Material Breach.** A breach by BUSINESS ASSOCIATE or BUSINESS ASSOCIATE’s agents of any material provision of this Amendment, as determined by UCLA, shall constitute a material breach of the Agreement. If UCLA determines that a material breach has occurred, UCLA, upon written notice to BUSINESS ASSOCIATE describing the breach, may take any of the following actions:

      1. Termination of the Agreement immediately if UCLA determines that (a) BUSINESS ASSOCIATE has breached a material term of this Amendment and (b) cure of the breach is not feasible;

      2. Termination of the Agreement unless BUSINESS ASSOCIATE, within five (5) business days, provides UCLA a plan to cure the breach and, within a period of fifteen (15) business days, cures the breach;

      3. In the case of a material breach of the Amendment, if it is not feasible for UCLA to terminate the Agreement, UCLA shall so notify BUSINESS ASSOCIATE. Upon UCLA’s request:

         i. BUSINESS ASSOCIATE shall, at its expense, provide a third party review of the outcome of any plan implemented under section 2.a.2. to cure the breach;

         ii. BUSINESS ASSOCIATE shall submit to a plan of monitoring and reporting by UCLA or its agents if UCLA determines it is necessary to assess BUSINESS ASSOCIATE’s compliance with the Amendment.

   b. **Effect of Termination – Return or Destruction of PHI Held By BUSINESS ASSOCIATE or BUSINESS ASSOCIATE’s Agents.** Upon termination, expiration or other conclusion of the Agreement for any reason, BUSINESS ASSOCIATE shall return or, at the option of UCLA, destroy all PHI received from UCLA, or created and received by BUSINESS ASSOCIATE on behalf of UCLA, that BUSINESS ASSOCIATE or its Agents still maintain in any form, and shall retain no copies of such PHI. Not less than thirty (30) calendar days after the termination of this Agreement, BUSINESS ASSOCIATE shall both complete such return or destruction and certify in writing to UCLA that such return or destruction has been completed.

      If BUSINESS ASSOCIATE states that return or destruction of UCLA’s PHI is not feasible, BUSINESS ASSOCIATE must provide UCLA with a written statement of the reason that return or destruction by BUSINESS ASSOCIATE or BUSINESS ASSOCIATE’S Agents is not feasible. If UCLA determines that return or destruction is not feasible, this Amendment shall remain in full force and effect and shall be applicable to any and all of UCLA’s PHI held by BUSINESS ASSOCIATE or BUSINESS ASSOCIATE’S Agents.

3. **Changes to the Amendment.**

   a. **Compliance with Law.** The parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that changes to this Amendment may be required to ensure compliance with such developments. The parties specifically agree to take such action as may be necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations and other applicable state and federal laws relating to the security or confidentiality of PHI.
b. **Negotiations.** In the event of a change in or interpretation of any state or federal law, statute, or regulation which materially affects the rights or obligations of either party under the Agreement or this Amendment, the parties agree to negotiate immediately in good faith any necessary or appropriate revisions to the Agreement. If the parties are unable to reach an agreement concerning such revisions within the earlier of sixty (60) calendar days after the date of notice seeking negotiations or the effective date of a change in law or regulation, then either party may immediately terminate this Agreement upon written notice to the other.

4. **Indemnification.**
   
   e. **Indemnification by BUSINESS ASSOCIATE.** BUSINESS ASSOCIATE agrees to defend at UCLA’s election, indemnify, and hold harmless UCLA, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys’ fees) or claims for injury or damages that are caused by or result from the acts or omissions of BUSINESS ASSOCIATE, its officers, agents or employees with respect to the use and disclosure of UCLA’s PHI.
   
   f. **Indemnification by UCLA.** UCLA agrees to defend at BUSINESS ASSOCIATE’s election, indemnify, and hold harmless BUSINESS ASSOCIATE, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys’ fees) or claims for injury or damages that are caused by or result from the acts or omissions of UCLA, its officers, agents or employees with respect to the use and disclosure of UCLA’s PHI.

5. **Miscellaneous Provisions.**
   
   a. **Assistance in Litigation or Administrative Proceedings.** BUSINESS ASSOCIATE shall make itself, and any employees or agents assisting BUSINESS ASSOCIATE in the performance of its obligations under the Agreement and this Amendment, available to UCLA at no cost to UCLA to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings against UCLA, its directors, officers, agents or employees based upon claimed violation of HIPAA, the HIPAA Regulations or other laws relating to security and privacy and arising out of the Agreement or this Amendment.
   
   b. **No Third Party Beneficiaries.** Nothing express or implied in this Amendment is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than UCLA, BUSINESS ASSOCIATE and their respective successors or assigns.
   
   c. **Notice to Secretary.** If UCLA knows of a pattern of activity or practice of BUSINESS ASSOCIATE that constitutes a material breach or violation of BUSINESS ASSOCIATE’s obligation under this Amendment, if the breach or violation continues, and if termination of this Amendment is not feasible, UCLA is required by the HIPAA regulations to report the problem to the Secretary of Health and Human Services.
   
   d. **Survival.** The obligations of BUSINESS ASSOCIATE under Sections 1(l), 1(m), 2(b), 4(a), 4(b), and 5(a) of this Amendment shall survive the termination of this Agreement.
   
   e. **Notices.** Any notices to be given to either party shall be made via U.S. Mail or express courier to the address given below and/or via facsimile to the facsimile telephone numbers listed below.
If to BUSINESS ASSOCIATE, to: With a copy (which shall not constitute notice) to:

________________________________________  __________________________________________

________________________________________  __________________________________________

________________________________________  __________________________________________

Attention: __________________________  Attention: __________________________

Fax: __________________________  Fax: __________________________

If to UCLA, to: With a copy (which shall not constitute notice) to:

________________________________________  __________________________________________

________________________________________  __________________________________________

________________________________________  __________________________________________

Attention: __________________________  Attention: __________________________

Fax: __________________________  Fax: __________________________

Each party may change its address and that of its representative for notice by giving notice in the manner provided above.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment to the Agreement.

The Regents of the University of California on behalf of UCLA Healthcare

[Name of BUSINESS ASSOCIATE]

________________________________________  __________________________________________

Signature  Signature

________________________________________  __________________________________________

Printed Name  Printed Name

________________________________________  __________________________________________

Title  Title

________________________________________  __________________________________________

Date  Date