

**American College of Surgeons  
Committee on Trauma  
Business Associate Agreement**

**Name of Hospital:** \_\_\_\_\_  
**Hospital Address:** \_\_\_\_\_  
**City, State, Zip:** \_\_\_\_\_  
**Effective Date:** \_\_\_\_\_

The hospital participates in the American College of Surgeons' Committee on Trauma (COT) Consultation/Verification Review Program in Trauma for Hospitals and/or the National Trauma Data Bank (NTDB). The COT is the oldest standing committee of the American College of Surgeons (ACS). Its membership is composed of surgeons of many medical specialties who have a special interest in trauma care. The COT is dedicated to improving the care of the injured patient through education, standard setting, and the monitoring of quality of care.

Both the Consultation/Verification Review Program in Trauma for Hospitals and the NTDB collect data, which are used to improve performance, explore trends in trauma care delivery, and create benchmarks for participating hospitals.

The COT requires the Hospital to disclose to the ACS and for the ACS to use patient 'Protected Health Information' (PHI) as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

HIPAA requires that the Hospital and the ACS enter into a Business Associate Agreement to protect PHI.

1. The Hospital agrees that the ACS may use the PHI received for the following purposes:
  - a. To set standards for quality, multidisciplinary trauma care delivered in numerous hospital settings nationwide;
  - b. To survey hospitals to assess compliance with those standards;
  - c. To analyze, aggregate, produce, and publish aggregated de-identified data on clinical patterns of diagnosis, treatment, and outcomes of trauma patients;
  - d. To produce reports of aggregated, de-identified data that describe the diagnosis, treatment, and outcomes of trauma patients;
  - e. To evaluate hospital performance, develop effective interventions to improve trauma care outcomes at the local and national level, and provide feedback in the form of an individual facility's data benchmarked against aggregated, de-identified regional and national data (NTDB).
2. The hospital and the ACS agree to the additional terms and provisions on the Term Sheet below in order to comply with the applicable requirements of HIPAA.

## TERM SHEET

### **TERMS REQUIRED UNDER THE STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, 45 CFR PART 160 AND PART 164, SUBPARTS A AND E (THE “PRIVACY RULE”).**

#### **Definitions**

Terms used, but not otherwise defined, in this Agreement will have the same meaning as those terms in the Privacy Rule. PHI will have the meaning ascribed to it in the Privacy Rule, but for the purposes of this Agreement will refer solely to PHI received from, or created or received by the ACS, its agents or subcontractors, on behalf of the Hospital. The ACS is a Business Associate and the Hospital is a Covered Entity under the terms of the Privacy Rule.

#### **General Obligations of the ACS**

- (a) The ACS agrees not to use or disclose PHI other than as permitted or required by this agreement or as required by law.
- (b) The ACS agrees to use appropriate safeguards to prevent use or disclosure of PHI by the ACS or its agents, other than as provided for by this Agreement and will, at its own expense and at its own site, provide the equipment and software services necessary to reasonably protect and safeguard the PHI consistent with industry standards of similarly situated business associates.
- (c) The ACS agrees to report to the Hospital any use or disclosure of PHI not authorized by this Agreement of which it becomes aware.
- (d) The ACS agrees to ensure that any agent, including a subcontractor, to whom it provides PHI will agree to comply with the same restrictions and conditions that apply to the ACS through this Agreement.
- (e) The ACS agrees to make its internal practices, books and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by the ACS on behalf of the Hospital, available to the Secretary of the U.S. Department of Health and Human Services (“Secretary”), during reasonable business hours, for purposes of the Secretary determining the Hospital’s compliance with the Privacy Rule.
- (f) The ACS agrees to document and account for disclosures of PHI and information related to such disclosures as would be required by the Privacy Rule if the Hospital made the same or similar disclosures.
- (g) The ACS agrees to provide to the Hospital or an Individual, within thirty (30) days, information collected in accordance with subsection (f) of this section to permit the hospital to respond to a request by an Individual for an accounting of disclosures of PHI.
- (h) The ACS agrees to mitigate, to the extent practicable, any harmful effect that is known to the ACS of a use or disclosure of PHI by the ACS in violation of the requirements of this Agreement.
- (i) The ACS agrees to amend PHI in accordance with instructions provided by the Hospital.
- (j) Each party agrees to indemnify and hold harmless the other party from direct losses and damages suffered by indemnified party as a result of the indemnifying party's breach of its obligations under the Agreement, including but not limited to direct losses and damages relating to third party claims. Under no circumstances, however, will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The parties' obligations under this section regarding indemnification will survive any expiration or termination of this Agreement.

### **Additional Uses and Disclosure Provisions**

- (a) Except as otherwise limited in this Agreement, the ACS may use PHI for the proper management and administration of the ACS or to carry out the legal responsibilities of the ACS.
- (b) Except as otherwise limited in this Agreement, the ACS may disclose PHI for the proper management and administration of the ACS, provided that disclosures are required by law, or the ACS otherwise obtains reasonable assurances from the person to whom the information is disclosed that the person will (i) protect the confidentiality of the PHI, (ii) use or further disclose it only as required by law or for the purpose for which it was disclosed to the person, and (iii) notify the ACS of any instances of which the person is aware that the confidentiality of the information has been breached.
- (c) Nothing in this Agreement will be interpreted to prevent the ACS from disclosing PHI in accordance with the Privacy Rule [42 CFR 164.502(j)(1)] concerning disclosures in the public interest, or other permissible uses or disclosures by a business associate as set forth in the Privacy Rule.

### **General Obligations of the Hospital**

- (a) Provisions for the hospital to inform the ACS of privacy practices and restrictions.
  - (i) The Hospital shall notify the ACS of any limitation(s) in the Hospital's Notice of Privacy Practices, to the extent that such limitation may affect the ACS's use or disclosure of PHI. The Hospital will make its Notice of Privacy Practices available to the ACS upon request.
  - (ii) The Hospital warrants that all disclosures of PHI made to the ACS are permissible disclosures under the Privacy Rule and that no Individual has restricted disclosure so as to make the disclosure to the ACS impermissible. The Hospital will notify the ACS of any restriction on the use or disclosure of PHI that the Hospital has agreed to in accordance with the Privacy Rule [45 CFR 164.522] if such restriction affects the ACS's use or disclosure of PHI.
- (b) Permissible requests by the hospital. The Hospital will not ask the ACS to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if undertaken by the Hospital; except as otherwise provided for in this Agreement.

## **ADDITIONAL PROVISIONS**

### **Term and Termination**

- (a) Term. The Term of this Agreement will begin on the Effective Date and will remain in effect until terminated by mutual agreement of the parties or in accordance with the termination provisions in subparagraph (b) below.
- (b) Termination for Cause. Either party may terminate this Agreement based on a material breach of this Agreement, provided that the non-breaching Party gives the breaching party thirty (30) days written notice of termination and the opportunity to remedy the breach, and the breach is not remedied during the notice period.
- (c) Effect of Termination. Except as provided in paragraph (b) of this sub-section, upon termination of this Agreement, for any reason, the ACS will, at the Hospital's direction, destroy all PHI received from the Hospital, or created or received by the ACS on behalf of the Hospital if the PHI has not yet been entered into the ACS's database. The ACS will retain no copies of the PHI, except to the extent that it has been entered into the ACS's database.

In the event that the ACS reasonably determines that destroying the PHI is infeasible due to inclusion of the PHI in the ACS's database or for other legitimate reason, the ACS will

give the Hospital a statement of reasons why the return or destruction of the PHI is infeasible. As the sole consequence of such determination, the ACS will extend the protections of this Agreement to such PHI and limit further its use and disclosure to those purposes that make the return or destruction infeasible, for so long as the ACS maintains such PHI.

The obligations of this sub-section (c) will survive any termination or expiration of this Agreement.

## **MISCELLANEOUS**

- (a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended and for which compliance is required.
- (b) Amendment. Any amendment to this Agreement must be in writing and signed by each of the Parties. The Parties agree to amend this Agreement from time to time as necessary for the Hospital to comply with the requirements of federal and applicable state law and regulations including the Privacy Rule and HIPAA. Either party may request that the other party amend this Agreement in order to comply with applicable state and federal law and regulations. If amendment of this Agreement is not achieved to the satisfaction of both parties, then either party may terminate this Agreement without penalty.
- (c) Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits the Hospital and the ACS to comply with HIPAA and applicable state and federal laws and regulations.
- (d) Assignment. Except as otherwise provided herein, neither Party may without the written consent of the other assign, subcontract, delegate or otherwise transfer this Agreement or any of its rights or obligations under this Agreement. Nor may either Party contract with third parties to perform any obligations required by this Agreement except as may be contemplated in this Agreement, without the other Party's prior written consent.
- (e) Severability. If any part of this Agreement is determined to be invalid, illegal or unenforceable by any Act of Congress, state legislature, or by any regulation issued by the United States or a state, or declared null and void by any court with valid jurisdiction, then the Parties will modify such part, if possible, to conform to the law, and the remaining parts will be fully effective and operative insofar as reasonably possible.
- (f) Entire Agreement. This Agreement constitutes the entire understanding and agreement between the Parties concerning the subject matter of this Agreement, and supersedes all prior negotiations, agreements and understandings between the Parties, whether oral or in writing, concerning its subject matter.

## SECURITY RULE AMENDMENT TO BUSINESS ASSOCIATE AGREEMENT

This Amendment to Business Associate Agreement (the "Amendment") is entered into as of \_\_\_\_\_ by and between The American College of Surgeons (the "Business Associate") and \_\_\_\_\_, ("Facility") (each "Party" and collectively the "Parties").

**WHEREAS**, the U. S. Department of Health and Human Services ("HHS") has issued final regulations, pursuant to the Administrative Simplification provision of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), governing the security of electronic protected health information ("EPHI") obtained, created or maintained by covered entities, including health care providers such as Facility (the "HIPAA Security Rule"); and

**WHEREAS**, Facility and Business Associate are parties to a Business Associate Agreement (The "Agreement") and the HIPAA Security Rule requires that Facility enter into this Amendment with Business Associate in order to protect the security of EPHI; and

**WHEREAS**, Business Associate and its employees, affiliates, agents or representatives access, create, obtain or maintain EPHI in carrying out their obligations to Facility; and

**WHEREAS**, the Parties desire to enter into this Amendment to protect security of EPHI and to amend any agreements between them with the execution of this Amendment;

**NOW, THEREFORE**, in consideration of the premises and mutual covenants hereinafter set forth, and for other valuable consideration, the receipt, adequacy and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Business Associate Covenants.

- 1.1 Business Associate shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that creates, receives, maintains or transmits on behalf of the Facility; and
- 1.2 Business Associate shall report to Facility promptly, but in no event later than 30 (thirty) business days of its discovery, any "security incident" of which it becomes aware, as such term is defined in the HIPAA Security Rule. At the request of Facility, Business Associate shall identify: the date of the security incident, the scope of the security incident, the Business Associate's response to the security incident and the identification of the party responsible for causing the security incident, if known.
- 1.3 Business Associate shall ensure that any agent, including a subcontractor, to whom it provides EPHI agrees in writing to implement reasonable and appropriate safeguards to protect EPHI.

2. Ratification of Agreement. Except as expressly modified herein, all other terms and conditions of the Agreement shall remain in full force and effect as written, and are hereby ratified and confirmed by Facility and Business Associate.

3. Effective Date. The provision of this Amendment shall become effective April 20, 2005 (the "Effective Date").

4. Miscellaneous. The Agreement and the Amendment represent the entire agreement of the parties with respect to the subject matter hereof. This Amendment is binding on and shall inure to the benefit of Facility and Business Associate and their respective legal representatives, successors and permitted assigns. Neither this Amendment nor the Agreement may be amended, except by a written agreement signed by both parties.

**HITECH AMENDMENT TO HOSPITAL PARTICIPATION AGREEMENT**

This HITECH Amendment (“Amendment”) is between the hospital identified above (“Hospital”) and the American College of Surgeons (“ACS”) and amends each and every agreement between the Hospital and ACS in which ACS is a Business Associate of Hospital (including, but not limited to, any and all Participation Agreements related to Hospital’s participation in the following ACS programs: NSQIP, Bariatric Accreditation, TQIP, Trauma, or Cancer (collectively, the “Participation Agreement(s)”). The parties agree as follows:

1. The parties acknowledge and agree that as a Business Associate, ACS must comply with relevant provisions of the HIPAA Security Rule and HIPAA Privacy Rule as required by the Health Information Technology for Economic and Clinical Health Act of 2009 and its associated regulations (“HITECH”), effective on the effective or enforcement dates thereof.
2. ACS agrees that it will implement policies and procedures to comply with applicable provisions of the HIPAA Security Rule and Privacy Rule, as required by HITECH.
3. ACS agrees that it will provide Hospital with written notice of any “Breach” of “Unsecured PHI,” discovered by ACS, its employees, officers, or other agents (as determined in accordance with the federal common law of agency). Notice shall be in writing and provided to without unreasonable delay and will include those elements required to be provided pursuant to HITECH.
4. ACS will comply with any amendments to HITECH, HIPAA, and any regulations promulgated thereunder that are applicable to Business Associate.
5. Capitalized terms in the HITECH Amendment shall have the meanings ascribed to them in HITECH, HIPAA, or their associated regulations.
6. To the extent there are any inconsistencies between this HITECH Amendment and the Participation Agreement(s), the terms of this HITECH Amendment will prevail.
7. The parties agree to amend this HITECH Amendment and/or the Participation Agreement(s) as required to ensure compliance by both parties with applicable laws, rules, and regulations.

*Gay L. Vincent*

**3/22/2011**

**Gay Vincent, CPA MBA, Chief Financial Officer**

**Date**

**Print Name and Title of person accepting on behalf of Hospital**

**Date**

**Signature of person accepting on behalf of Hospital**

**Date**