

## BUSINESS ASSOCIATE AND DATA USE AGREEMENT

NAME OF COVERED ENTITY: \_\_\_\_\_

COVERED ENTITY FEIN/TAX ID: \_\_\_\_\_

COVERED ENTITY ADDRESS: \_\_\_\_\_

\_\_\_\_\_,                      \_\_\_\_\_                      \_\_\_\_\_  
City                                      State                                      Zip

This **Business Associate and Data Use Agreement** (“Agreement”) is effective as of the date signed by both parties (“Effective Date”) between \_\_\_\_\_ (“Covered Entity”) and the American College of Surgeons (“ACS”) and shall continue until terminated in accordance with Section 10 below.

WHEREAS, Covered Entity desires to participate in one or more quality improvement programs administered by ACS (“ACS Program”) which requires Covered Entity to allow ACS to have access to Covered Entity’s Protected Health Information (“PHI”); and

WHEREAS, Covered Entity and ACS may have entered into one or more certain written agreement(s) regarding Covered Entity’s participation in the ACS program(s) (“Underlying Agreement(s)”).

NOW THEREFORE the parties agree as follows:

1. General Business Associate and Data Use Provisions. The ACS Program requires Covered Entity to Disclose to ACS and for ACS to Use and Disclose patient PHI, including Electronic Protected Health Information (“EPHI”), as those terms are defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and the regulations issued under HIPAA and HITECH (collectively, the “HIPAA Regulations”). These Uses and Disclosures are for purposes of ACS providing services to Covered Entity meant to improve the quality of surgical or other medical care to patients, including conducting data analyses, quality assessment, accreditation or verification that relate to Covered Entity’s Health Care Operations. The ACS Program also may from time to time require the Disclosure of PHI in the form of a Limited Data Set for ACS to provide services to Covered Entity related to its Health Care Operations and for Research purposes. The HIPAA Regulations require Covered Entity and ACS to enter into a Business Associate Agreement and a Data Use Agreement to protect PHI and EPHI and Limited Data Sets.
  
2. Definitions. Capitalized terms used but not otherwise defined in this Agreement will have the meaning ascribed to them in the HIPAA Regulations. PHI and EPHI will have the meaning ascribed to them in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Covered Entity to

ACS or a Subcontractor of ACS, or created by ACS or its Subcontractor on behalf of Covered Entity. Unless otherwise specified, PHI will include EPHI for purposes of this Agreement. Limited Data Set will have the meaning ascribed to “Limited Data Set” in the Privacy Rule, but for the purposes of this Agreement will refer solely to Limited Data Sets transmitted from or on behalf of Covered Entity to ACS or a Subcontractor of ACS, or created by ACS or its Subcontractor on behalf of Covered Entity. The parties agree that ACS is a Business Associate and Covered Entity is a Covered Entity under the terms of the HIPAA Regulations.

3. Specific Permitted Uses and Disclosures. Except as otherwise specified in this Agreement, ACS may Use or Disclose PHI on behalf of, or in order to provide services to, Covered Entity only to the extent such Use or Disclosure is reasonably necessary to facilitate Covered Entity’s participation in the ACS Program, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Covered Entity. Without limiting the generality of the foregoing, Covered Entity further agrees that ACS may Use and Disclose the PHI received for the following specific purposes:

- a. To analyze, aggregate, produce and publish data on clinical patterns of diagnosis, treatment and outcomes of patients to assist with Health Care Operations;
- b. To produce reports of aggregated, de-identified data and data not identifiable by contributing entity that describe the diagnosis, treatment and outcomes of patients to assist with Health Care Operations;
- c. To evaluate performance, develop effective interventions to improve outcomes at the national and local level, and provide feedback in the form of benchmarking and other reports to assist with Health Care Operations; and
- d. To create, Use and share Limited Data Sets with other participants in the same ACS Program and with other researchers for Research in the area of health care, subject to the provisions of Sections 4(g) and 6 below.

4. General Uses and Disclosures.

- a. Except as otherwise limited in this Agreement, ACS may Use PHI for the proper management and administration of ACS or to carry out the legal responsibilities of ACS.
- b. Except as otherwise limited in this Agreement, ACS may Disclose PHI for the proper management and administration of ACS, provided that Disclosures are Required By Law, or ACS otherwise obtains reasonable assurances from the person to whom the PHI is disclosed that the person will (i) protect the confidentiality and security 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 ACS of any instances of which the person is aware that the confidentiality or security of the PHI has been breached.

- c. Nothing in this Agreement will be interpreted to prevent ACS from Disclosing PHI in accordance with the HIPAA Regulations, 45 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 HIPAA Regulations.
- d. Except as otherwise limited in this Agreement, ACS may Use and Disclose PHI to provide Data Aggregation services to Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).
- e. ACS may de-identify PHI for purposes related to Covered Entity's participation in the ACS program, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. ACS may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is otherwise consistent with this Agreement.
- f. ACS may partially de-identify PHI to create a Limited Data Set for purposes related to Covered Entity's participation in the ACS Program, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).
- g. ACS may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Sets to a third party for Research, Public Health, or Health Care Operations purposes in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Covered Entity's participation in the ACS Program or for ACS's research purposes; (ii) is otherwise consistent with this Agreement; and (iii) would not violate the HIPAA Regulations if done by Covered Entity.

5. Obligations of ACS as Business Associate.

- a. ACS agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required by Law.
- b. ACS agrees to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to EPHI, to prevent Use or Disclosure of PHI by ACS or its Subcontractors other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the EPHI that ACS creates, receives, maintains or transmits on behalf of Covered Entity. Without limiting the foregoing, ACS and/or its Subcontractors will, at its own expense, provide the equipment and software services necessary to reasonably protect and

safeguard the PHI consistent with industry standards of similarly situated business associates.

- c. In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), ACS agrees to ensure that any Subcontractor to whom it provides or who accesses Covered Entity's PHI or EPHI will agree to comply with the same restrictions and conditions that apply to ACS through this Agreement, including the implementation of reasonable and appropriate safeguards to protect EPHI and the provisions of Section 6 below.
- d. ACS agrees to make its internal practices, books and records relating to the Use and Disclosure of PHI and EPHI received from, or created or received by ACS on behalf of Covered Entity and ACS's Administrative, Physical and Technical Safeguards for EPHI, available to the Secretary of the U.S. Department of Health and Human Services ("Secretary") for purposes of the Secretary determining Covered Entity's compliance with the HIPAA Regulations.
- e. If PHI provided to ACS constitutes a Designated Record Set, ACS agrees to provide Covered Entity with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Covered Entity's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to PHI. If an Individual requests an electronic copy of PHI, ACS agrees to provide PHI in an electronic form and format requested by the Individual if it is readily producible or, if not, in an electronic form and format as agreed to by ACS and Covered Entity. In the event an Individual contacts ACS or its Subcontractor directly about gaining access to his or her PHI, ACS will not provide such access but rather will promptly forward such request to Covered Entity.
- f. If PHI provided to ACS, or to which ACS otherwise has access, constitutes a Designated Record Set, ACS agrees to make timely amendment(s) to such PHI as Covered Entity may reasonably direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts ACS or its Subcontractor directly about making amendments to his or her PHI, ACS will not make such amendments, but rather will promptly forward such request to Covered Entity.
- g. ACS agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, ACS agrees to provide promptly to Covered Entity or an Individual, upon Covered Entity's reasonable request, information collected in accordance with this subsection in order to permit Covered Entity to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this subsection will not

apply with respect to Disclosures made to carry out Covered Entity's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA Regulations.

- h. ACS agrees to mitigate, to the extent practicable, any harmful effect that is known to ACS of an improper Use or Disclosure of PHI or EPHI by ACS.
- i. ACS agrees to promptly report to Covered Entity any Use or Disclosure of PHI not authorized by this Agreement of which it becomes aware and any Security Incident of which it becomes aware. In addition, in the event of an unauthorized Use or Disclosure that constitutes a Breach of Unsecured PHI (as defined by HITECH), ACS will notify Covered Entity without unreasonable delay but in no event later than thirty (30) calendar days following the Discovery of such Breach, or within such time as required by applicable state law, whichever is shorter. Such notice shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by ACS to have been, accessed, acquired, used, or disclosed during the Breach, and such other available information as is required to be included in the notification to the individual under 45 CFR 164.404(c) and any applicable state law.
- j. To the extent ACS is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR part 164, ACS agrees to comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s).
- k. ACS agrees to Use and Disclose only the minimum PHI necessary to accomplish the intended purpose of the Use or Disclosure of PHI.
- l. ACS does not Use or Disclose PHI for marketing purposes and agrees to comply with 45 CFR 164.508(a)(3).
- m. ACS agrees to comply with 45 CFR 164.502(a)(5)(ii) regarding the prohibition against the sale of PHI.

6. Data Use Agreement Obligations. With respect to the Limited Data Sets that ACS may create, Use and Disclose for Research purposes pursuant to Section 3(d) herein, ACS agrees that it:

- a. Will Use the Limited Data Set only for such Research purposes and will Disclose the Limited Data Set only to participants in the same ACS Program and other researchers for Research in the area of health care in accordance with the provisions of 45 CFR 164.512(i);
- b. Will not Use or further Disclose the Limited Data Set in a manner that would violate the HIPAA Regulations if done by Covered Entity;

- c. Will not Use or Disclose the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law;
- d. Will use reasonable and appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement, including Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set that it creates, receives, maintains, or transmits on behalf of Covered Entity as required by 45 CFR 164.314;
- e. Will promptly report to Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware and any Security Incident involving the Limited Data Set of which it becomes aware;
- f. Will ensure that any ACS Program participants or other researchers, and Subcontractors to whom it provides the Limited Data Set, contractually agree to the same restrictions and conditions that apply to ACS with respect to such information; and
- g. Will not use the Limited Data Set to identify or contact the Individuals who are the subject of the information. Nothing in this subsection will be interpreted to limit ACS's ability to provide its Data Aggregation and analysis services as otherwise provided by this Agreement.

7. General Obligations of Covered Entity.

- a. Covered Entity Agrees to comply with 42 C. F. R. § 164.520
- b. Covered Entity shall notify ACS of any limitation(s) in Covered Entity's Notice of Privacy Practices, to the extent that such limitation may affect ACS's Use or Disclosure of PHI.
- c. To Covered Entity's knowledge, as of the Effective Date, all Disclosures of PHI made to ACS are permissible Disclosures under the HIPAA Regulations, and no Individual has restricted Disclosure so as to make the Disclosure to ACS impermissible. Covered Entity will notify ACS of any restriction on the Use or Disclosure of PHI that Covered Entity has agreed to in accordance with the HIPAA Regulations, 45 CFR 164.522, if such restriction affects ACS's Use or Disclosure of PHI.
- d. Covered Entity will not ask ACS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Covered Entity; provided that Covered Entity may, as otherwise permitted under this Agreement, request that ACS Use or Disclose PHI for the purposes of Data Aggregation or the proper management and administrative activities of ACS or to carry out the legal responsibilities of ACS, as provided for in 45 CFR 164.504(e)(4).

8. Insurance. ACS agrees to maintain business liability insurance which ACS determines is commercially reasonable and sufficient to cover its obligations under this Agreement.
9. Indemnification. Each party (the “Indemnifying Party”) agrees to indemnify, defend and hold harmless the other party (the “Indemnified Party”), its directors, officers, employees and agents from any and all liabilities, claims, damages, loss and costs (including reasonable attorney’s fees) to the extent arising from the negligent acts or omissions or willful misconduct of the Indemnifying Party related to this Agreement and/or a violation of HIPAA related to this Agreement. Notwithstanding anything herein to the contrary, neither party shall be liable for indirect, special, or consequential damages.
10. Termination.
  - a. This Agreement shall become effective on the Effective Date and shall remain in effect until termination of all of the Underlying Agreements, if applicable, or until termination as set forth in this Agreement.
  - b. This Agreement may be terminated as follows:
    - (i) By written agreement of both parties;
    - (ii) By either party upon written notice if the other party (“Breaching Party”) is in breach of a material provision of this Agreement and the Breaching Party fails to cure the material breach within thirty (30) days after receiving written notice of the material breach; or
    - (iii) If there is no Underlying Agreement, by thirty (30) days written notice from Covered Entity to ACS.
  - c. Termination of this Agreement shall terminate all Underlying Agreements that require Covered Entity to submit PHI to ACS.
11. Effect of Termination on ACS Obligation to Destroy or Protect Data. Except as provided below, upon termination of this Agreement for any reason, ACS will, at Covered Entity’s direction, return or destroy all PHI received from Covered Entity, or created or received by ACS on behalf of Covered Entity, and ACS will retain no copies of the PHI. Data contained in a Limited Data Set shall not be subject to the obligations of this section provided that the Data Use provisions pertaining to such Limited Data Set that are set forth above will survive any termination or expiration of the Agreement. In the event that ACS reasonably determines that returning or destroying the PHI is infeasible due to inclusion of the PHI in ACS’s database or for other legitimate reasons, ACS will give Covered Entity a statement of reasons why the return or destruction of the PHI is infeasible. As the sole consequence of such determination, 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 ACS maintains such PHI. The obligations of this section will survive any termination or expiration of this Agreement.

12. Effect of Termination on Provision of Data to ACS. The parties acknowledge and agree that the provision of any PHI to ACS in accordance with this Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the parties agree that Covered Entity will refrain from submitting PHI to ACS, and ACS will refrain from accepting PHI from Covered Entity.
13. Regulatory References. A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended and for which compliance is required.
14. 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 parties to comply with the requirements of federal and applicable state law and regulations. Either party may request that the other party amend this Agreement in order to comply with applicable state and federal law and regulations. If after a reasonable period of good faith negotiation, an amendment of this Agreement is not achieved to the satisfaction of both parties, then either party may terminate this Agreement and the Underlying Agreement(s), if applicable, without penalty. In the event the parties engage in negotiations undertaken in accordance with this Section, the parties may suspend during such period of negotiation any provision of this Agreement requiring or obligating either party to Use or Disclose PHI in a manner that either party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.
15. Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Covered Entity and ACS to comply with the HIPAA Regulations, HITECH, and applicable state and federal laws and regulations.
16. Relationship to the Underlying Agreement(s). If the parties have entered into an Underlying Agreement(s), it is the intent of the parties that the terms of the Underlying Agreement(s) be interpreted so as to cause the Underlying Agreement(s) to comply with the HIPAA Regulations. Accordingly, this Agreement shall amend the Underlying Agreement(s) to the extent provided herein regardless of whether this Agreement formally satisfies the requirements of the Underlying Agreement(s) for amendment of the Underlying Agreement(s). To the extent any provisions of this Agreement conflict with the terms of the Underlying Agreement(s), this Agreement shall govern.
17. Assignment. Except as otherwise provided herein, neither party may without the written consent of the other assign, delegate or otherwise transfer this Agreement or any of its rights or obligations under this Agreement.
18. 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.
19. 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.

20. Jurisdiction. This Agreement is governed by the laws of the State of Illinois and venue for resolution of any disputes shall reside in the Federal or State courts in Cook County, Illinois.
21. Third Party Beneficiaries. ACS and Covered Entity agree that Individuals whose PHI is Used or Disclosed to ACS or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement.
22. Waiver. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
23. Relationship of the Parties. The parties are independent contractors of each other. Nothing in this Agreement shall be construed to create an employer/employee, joint venture, or other similar relationship between the parties. Neither party shall have the right to exercise control or direction over the business of the other party.
24. Authority. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the party he or she represents, and that this Agreement will be binding on such party, and its officers, directors, agents, and employees.
25. Notices. Any notices required pursuant to this Agreement shall be in writing and sent by US Mail, personal delivery, next-day express mail, or by facsimile addressed as identified below:

American Colleges of Surgeons  
Attn: Gay Vincent  
633 North Saint Clair Street  
Chicago, IL 60611  
Fax 312-202-5025

Covered Entity

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**Print Name and Title of person on behalf of the  
American College of Surgeons**

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**Signature of person on behalf of the  
American College of Surgeons** **Date**

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**Print Name and Title of person accepting  
on behalf of Covered Entity**

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**Signature of person accepting on behalf of  
Covered Entity** **Date**