



**MULTISPECIALTY Reduced Volume
HOSPITAL PARTICIPATION AGREEMENT
INCLUDING BUSINESS ASSOCIATE AND DATA USE AGREEMENTS**

NAME OF HOSPITAL: _____
HOSPITAL FEIN: _____
HOSPITAL ADDRESS: _____
_____, _____, _____
City State Zip

This **Hospital Participation Agreement Including Business Associate and Data Use Agreements** ("Agreement") is entered into as of _____ ("Effective Date") between _____ ("Hospital") and the American College of Surgeons ("ACS") and shall continue through the end of the participation period as defined in Section 1, Participation Period. WHEREAS, Hospital desires to participate in the ACS National Surgical Quality Improvement Program ("ACS NSQIP") and ACS desires to receive data from the Hospital for inclusion in the ACS NSQIP.

1. Participation Period. The participation period is defined as the period beginning on the first day of the month that the first Nurse Reviewer attends the initial training session and will continue for twelve (12) consecutive months thereafter. A letter confirming the commencement of the participation period and its end dates will be sent once the nurse has registered and been confirmed for the initial nurse training session. Once commenced, the participation period may not be stopped at any time during the 12-month period.

2. Contribution of Data. The Hospital agrees to contribute its ACS NSQIP Data at least weekly to the ACS NSQIP in the format set forth on the acsnsqip.org web site in a document named "Data Collection Form", which is subject to change by the ACS NSQIP Advisory Committee, and in accordance with the data reliability standards set by the ACS NSQIP. The Hospital agrees to contribute *all* cases that meet the program inclusion criteria in the areas of general and vascular surgery, urology, neurosurgery, orthopedics, ENT, plastic, thoracic, and gynecological surgery. At a minimum, the Hospital agrees to contribute 22 cases for each 8-day cycle. In order to ensure the statistical viability of the ACS NSQIP, the Hospital agrees to contribute a minimum of 900 cases (42 complete cycles) during 12 months of participation. The Hospital agrees to contribute the requisite number of cases annually as detailed in the application document named "Case Volume and SCNR Worksheet". Data are submitted via a web-based data collection system with standardized fields. The Hospital shall retain ownership of the data it submits to the ACS NSQIP and, subject to the terms and conditions set forth herein, hereby grants to ACS a non-exclusive, perpetual, irrevocable license to utilize the ACS NSQIP Data contributed to the ACS NSQIP and to share it with other participants for purposes of quality improvement/benchmarking in the area of health care, or for related Research purposes in the area of health care (as further described in Section 11.b.iv. below).

3. Fees. The Hospital agrees to pay to ACS the annual sum of \$10,000 for participation in the ACS NSQIP for the twelve month period as defined in Section 1, Participation Period. Additional fees may apply as described in Section 9, Data Collectors, and Section 10, Audits.

4. Payment. Unless requested earlier by Hospital, ACS will provide an invoice to Hospital at the time the contract is submitted for ACS signature. Payment is due upon receipt.
5. Services Provided to Hospital. Attached hereto and incorporated herein as Exhibit A is a schedule of Services Provided to Hospital that ACS will make available or ensure are available during the participation period of this Agreement.
6. Hospital Requirements. Attached hereto and incorporated herein as Exhibit B is a schedule of Hospital requirements for continued participation in the ACS NSQIP.
7. Access to and Use of Data. The Hospital will have continuous access to the Hospital's own ACS NSQIP Data. The Hospital will also have continuous access to cumulative non-risk-adjusted ACS NSQIP Data of all contributors, in a manner that does not identify or permit identification of the contributors, and presented for the purpose of comparison to national averages and peer groups. Notwithstanding the ownership rights of contributing hospitals to the data submitted to the ACS NSQIP, ACS owns all right, title, and interest in the ACS NSQIP Database and the aggregated data contained therein. ACS hereby grants to the Hospital a limited, non-exclusive, revocable license to utilize these non-risk-adjusted ACS NSQIP Data for appropriate internal purposes only. The ACS NSQIP will provide reports to the Hospital from time to time, which will contain risk-adjusted ACS NSQIP Data. ACS hereby grants the Hospital a non-exclusive license to use the risk-adjusted data for appropriate internal and external purposes.
8. De-identification of Data (as to Hospital's Identity). ACS will not release the Hospital's ACS NSQIP Data in any format or circumstance that identifies the Hospital or its medical or professional staff or employees as the contributor of its specific data, except to the Hospital, as required by legal process, or as requested by the Hospital. If any legal demand for the Hospital ACS NSQIP Data is made upon ACS, ACS will promptly notify the Hospital so that the Hospital may, at its option, challenge the validity of the legal process. The provisions of this Section 8 shall survive any termination or expiration of this Agreement.
9. Data Collectors. The Hospital agrees to dedicate the required number of nurse data collectors as determined by Hospital's surgical volume. If the Hospital is required or desires to hire more than one nurse to act as data collector, then an additional fee of \$8,900 will be applied for each additional nurse. Replacement and backup nurses and non-nurse staff may attend the SCNR training for a fee of \$2,500 per individual trained.
10. Audits. In order to monitor the quality of the data entered into the ACS NSQIP system, Hospital agrees that ACS or its agents may from time to time conduct on-site audits of Hospital data and collection procedures. ACS will provide at least five business days notice of an on-site audit. To the extent that medical record audits are conducted, such audits will be limited to the minimum necessary portions of the record needed for the audit. Additional audits may be required by the program or requested by the Hospital for an additional fee of \$3500 per audit.
11. Business Associate and Data Use Provisions. The ACS NSQIP requires the Hospital to Disclose to ACS and for ACS to Use and Disclose patient Protected Health Information ("PHI"), including Electronic Protected Health Information ("EPHI"), as those terms are defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations issued thereunder--i.e., 45 CFR Parts 160 and 164(the "HIPAA Regulations"). These Uses and Disclosures are for purposes of conducting data analyses that relate to the hospital's Health Care Operations, including but not limited to Data Aggregation and quality assessment. The ACS NSQIP 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 Hospital related to its Health Care Operations and for Research purposes. The HIPAA Regulations require the Hospital and ACS to enter into a Business Associate Agreement and a Data Use Agreement to protect PHI and EPHI and Limited Data Sets. The parties agree that the provisions of this Section 11 constitute the equivalent of a Business Associate Agreement and a Data Use Agreement for purposes of HIPAA.

- a. 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 the Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of the Hospital. 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 the Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of the Hospital. The parties agree that ACS is a Business Associate and the Hospital is a Covered Entity under the terms of the HIPAA Regulations.
- b. 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, Hospital to the extent such Use or Disclosure is reasonably necessary to facilitate Hospital's participation in the ACS NSQIP, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by the Hospital. Without limiting the generality of the foregoing, the Hospital further agrees that ACS may Use and Disclose the PHI received for the following specific purposes:
- i. To analyze, aggregate, produce and publish data on clinical patterns of diagnosis, treatment and outcomes of patients to assist with Health Care Operations;
 - ii. To produce reports of aggregated, de-identified data and data not identifiable by contributing hospital that describe the diagnosis, treatment and outcomes of patients to assist with Health Care Operations;
 - iii. To evaluate hospital performance, develop effective interventions to improve outcomes at the national and local level, and provide feedback in the form of an individual facility's ACS NSQIP Data benchmarked against regional and national ACS NSQIP Data to assist with Health Care Operations; and
 - iv. To create, Use and share Limited Data Sets with ACS NSQIP participants and with other researchers for Research in the area of health care, subject to the provisions of Subsection 11.c.vii. and 11.e. below.
- c. General Uses and Disclosures
- i. 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.
 - ii. 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 (a) protect the confidentiality and security of the PHI, (b) Use or further Disclose it only as Required By Law or for the purpose for which it was disclosed to the person, and (c) notify ACS of any instances of which the person is aware that the confidentiality or security of the PHI has been breached.
 - iii. 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.

- iv. Except as otherwise limited in this Agreement, ACS may Use and Disclose PHI to provide Data Aggregation services to Hospital as permitted by 45 CFR 164.504(e)(2)(i)(B).
- v. ACS may de-identify any PHI, 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.
- vi. ACS may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).
- vii. 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 Hospital's participation in the ACS NSQIP or for ACS's research purposes; (ii) is otherwise consistent with this Agreement; and (iii) would not violate the HIPAA Regulations if done by Hospital. Consistent with the HIPAA Regulations and HHS' December 3, 2002 Guidance Document, the term Health Care Operations includes Data Aggregation.

d. Obligations of ACS as Business Associate

- i. ACS agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.
- ii. ACS agrees to use appropriate safeguards to prevent Use or Disclosure of PHI by ACS or its agents or 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 the Hospital. 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.
- iii. ACS agrees to promptly report to the Hospital 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.
- iv. ACS agrees to ensure that any agent, including a subcontractor, to whom it provides or who accesses the Hospital'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 11.e. below.
- v. 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 the Hospital 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"), during reasonable business hours, for purposes of the Secretary determining the Hospital's compliance with the HIPAA Regulations.
- vi. If PHI provided to ACS, or to which ACS otherwise has access, constitutes a Designated Record Set, ACS agrees to provide Hospital with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Hospital'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 Protected Health Information. In the event an

Individual contacts ACS or its agent or subcontractor directly about gaining access to his or her PHI, ACS will not provide such access but rather will promptly forward such request to Hospital.

- vii. 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 the Hospital may reasonably direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts ACS or its agent or subcontractor directly about making amendments to his or her PHI, ACS will not make such amendments, but rather will promptly forward such request to Hospital.
- viii. ACS agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Hospital 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 Hospital or an Individual, upon Hospital's reasonable request, information collected in accordance with this subsection in order to permit Hospital 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 Hospital'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.
- ix. 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.

e. Data Use Agreement Obligations. With respect to the Limited Data Sets that ACS may create, Use and Disclose for research purposes pursuant to Section 11.b.iv herein, ACS agrees that it:

- i. will Use the Limited Data Set only for such Research purposes and will Disclose the Limited Data Set only to participants in ACS NSQIP and other researchers for Research in the area of health care in accordance with the provisions of 45 CFR 164.512(i);
- ii. will not Use or further Disclose the Limited Data Set in a manner that would violate the HIPAA Regulations if done by the Hospital;
- iii. will not Use or Disclose the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law;
- iv. 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 the Hospital as required by 45 CFR 164.314;
- v. will promptly report to the Hospital 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;
- vi. will ensure that any ACS NSQIP participants or other researchers, and any agents or 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
- vii. 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.

f. General Obligations of the Hospital

- i. The Hospital represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. The Hospital will provide ACS with a copy of its Notice of Privacy Practices upon request.
- ii. The Hospital shall notify ACS of any limitation(s) in the Hospital's Notice of Privacy Practices, to the extent that such limitation may affect ACS's Use or Disclosure of PHI.
- iii. The Hospital will provide ACS with any changes in, revocation of, or permission by an Individual to Use or Disclose PHI, if such changes affect ACS's permitted or required Uses and Disclosures.
- iv. To the Hospital'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. The Hospital will notify ACS of any restriction on the Use or Disclosure of PHI that the Hospital has agreed to in accordance with the HIPAA Regulations, 45 CFR 164.522, if such restriction affects ACS's Use or Disclosure of PHI.
- v. The Hospital will not ask ACS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by the Hospital; provided that the Hospital 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).

12. Hospital's Confidential Business Information. In addition to the patient confidentiality protections above, ACS will take reasonable steps to protect the confidentiality of all other, non-patient information concerning the Hospital that it receives or generates in connection with this Agreement and that the Hospital designates as confidential. ACS will use such information solely to carry out this Agreement and will not disclose such information without the Hospital's prior written approval or as Required By Law. The provisions of this Section 12 shall survive any termination or expiration of this Agreement.

13. Use of Name. Neither ACS nor the Hospital shall use the name or logo of the other party or of any of its affiliates, or any variation or acronym thereof, without the prior written consent of the other party, except that ACS may include the name of the Hospital in lists of participants in the ACS NSQIP, and the Hospital may state that the Hospital participates in the ACS NSQIP.

14. Termination. ACS reserves the right to terminate this Agreement prior to the end of a twelve-month participation period, upon thirty (30) days prior written notice to the Hospital, either if the Hospital materially fails to fulfill the terms of the Agreement or materially violates its conditions. Hospital may withdraw from/terminate this Agreement at any time. In either case no refund of fees will be due. ACS may also terminate this Agreement prior to the end of a participation period if ACS suspends data collection under the ACS NSQIP program, in which case ACS will refund to Hospital the pro rata portion of fees paid by Hospital for the unfulfilled portion of the participation period.

15. 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 the Hospital's direction, return or destroy all PHI received from the Hospital, or created or received by ACS on behalf of the Hospital, 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 reason, 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, 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.

16. 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 the Hospital will refrain from submitting PHI to ACS, and ACS will refrain from accepting PHI from the Hospital.

17. Force Majeure. Neither party shall be liable for failure to meet any requirements of this Agreement, and this Agreement may not be terminated for such cause, if such failure is due to electrical outage, strike, natural disaster or other event beyond the control of the party, which makes performance impossible or impractical.

18. Miscellaneous.

a. 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.

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 HIPAA 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 without penalty. In the event the parties engage in negotiations undertaken in accordance with this subsection, 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.

c. Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits the Hospital and 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, delegate or otherwise transfer this Agreement or any of its rights or obligations under this Agreement.

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.

g. 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.

h. Third Party Beneficiaries. ACS and the Hospital agree that Individuals whose PHI is Used or Disclosed to ACS or its agents or subcontractors under this Agreement are not third-party beneficiaries of this Agreement.

i. 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.

j. 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.

k. 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.

l. 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 College of Surgeons | Participating Hospital: |
| Attn: Gay Vincent | |
| 633 North Saint Clair Street | |
| Chicago, IL 60611 | |
| Fax: 312-202-5025 | |

[The remainder of this page has been intentionally left blank.]

**Gay Vincent, Chief Financial Officer
American College of Surgeons**

Date

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

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

Date