

Trauma Quality Improvement Program HOSPITAL PARTICIPATION AGREEMENT

NAME OF HOSPITAL: Natividad Medical Center

HOSPITAL FEIN: 94-6000524

HOSPITAL ADDRESS: 1441 Constitution Blvd.

Salinas,

City

CA

State

93906

Zip

This **Hospital Participation Agreement** ("Agreement") is effective January 25, 2016 ("Effective Date"), between the County of Monterey, a political subdivision of the State of California, on behalf of Natividad Medical Center ("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 the Hospital participates in the ACS National Trauma Data Bank ("NTDB"), which is a voluntary database program developed and maintained by the American College of Surgeons Committee on Trauma ("ACS COT") that aggregates trauma registry data; and

The ACS COT has developed the Trauma Quality Improvement Program ("ACS COT TQIP"), which uses data transmitted to the NTDB to provide reports, training, and other tools to assist hospitals and health centers in measuring trauma patient outcomes as part of their quality improvement activities;

WHEREAS, Hospital desires to participate in the ACS COT TQIP and ACS desires to receive data from the Hospital for inclusion in the ACS COT TQIP and to provide the services as described in this Agreement.

1. Term. The term of this Agreement ("Term") is from January 25, 2016 through January 24, 2021. This Agreement may be terminated pursuant to Section 12 of this Agreement.
2. Contribution of Data. The Hospital agrees to contribute its data (hereinafter referred to as "TQIP Data") to the NTDB for the TQIP in accordance with the National Trauma Data Standard (NTDS) Data Dictionary which is subject to change by the ACS COT. Hospital will transmit all trauma records that meet inclusion criteria through the data collection process provided by ACS within the schedule required by ACS. The Hospital shall retain ownership of its TQIP Data and, subject to the terms and conditions set forth herein, hereby grants to ACS a non-exclusive, perpetual, irrevocable license to utilize the TQIP Data 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 the Business Associate and Data Use Agreement executed by the parties).
3. Fees. In exchange for the services that ACS provides to Hospital in ACS COT TQIP, Hospital agrees to pay ACS an annual participation fee for ACS COT TQIP as described on Exhibit C. ACS may adjust this fee from time to time and will provide at least 60 days' advance notice of any adjustment in fees by publishing annual fees on the TQIP website. In addition, Hospital agrees to pay additional fees in connection with audits as described in Section 9.
4. Payment. Unless requested earlier by Hospital, ACS will provide an invoice to Hospital at the time the contract has been signed by both parties. The County Auditor-Controller shall pay the amount certified within 30 days of receiving the certified invoice. ACS will invoice Hospital upon annual renewal of this Agreement, until terminated.

5. Services Provided to Hospital. Attached hereto and incorporated herein as Exhibit A is a schedule of services to be provided to the Hospital by ACS.
6. Hospital Requirements. Attached hereto and incorporated herein as Exhibit B is a schedule of Hospital requirements for continued participation in the ACS COT TQIP. Hospital agrees that it shall continuously satisfy all requirements listed on Exhibit B throughout the Term of this Agreement.
7. Access to and Use of Data. The Hospital will have continuous access to the Hospital's own TQIP Data. The Hospital will also have continuous access to cumulative non-risk-adjusted ACS COT TQIP 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 Hospital to its own TQIP Data, ACS owns all right, title, and interest in the NTDB, the ACS COT TQIP 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 COT TQIP data for appropriate internal purposes only. The ACS will provide reports to the Hospital from time to time, which will contain risk-adjusted ACS COT TQIP data. ACS hereby grants the Hospital a non-exclusive license to use the risk-adjusted ACS COT TQIP data for appropriate internal and external purposes.
8. De-identification of Data (as to Hospital's Identity). ACS will not release the Hospital's TQIP 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 TQIP 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. Audits. In order to monitor the quality of the data, 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 ten 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. It is anticipated that audits will be conducted remotely or in-person, based on data quality considerations. If more than one audit in a three year period is required by ACS or requested by the Hospital, there will be an additional fee of \$2500 per audit.
10. Hospital's Confidential Business Information. ACS will take reasonable steps to protect the confidentiality of non-patient information concerning the Hospital that it receives or generates in connection with this Agreement and information 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 10 shall survive any termination or expiration of this Agreement.
11. 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 COT TQIP, and the Hospital may state that the Hospital participates in the ACS COT TQIP.
12. Termination. ACS may terminate this Agreement at any point during the Term by giving thirty (30) days prior written notice to the Hospital 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 if ACS suspends data collection under the ACS COT TQIP program, in which case ACS will refund to Hospital the pro rata portion of fees paid by Hospital for the unfulfilled portion

of the year for which the annual fee was paid. This Agreement shall automatically terminate upon the termination of the Business Associate and Data Use Agreement.

13. Effect of Termination on Provision of Data to ACS COT TQIP. The parties acknowledge and agree that the provision of any protected health information ("PHI") to ACS in accordance with this Agreement is conditioned upon this Agreement and the Business Associate and Data Use Agreement being in full force and effect. Therefore, upon termination of this Agreement or the Business Associate and Data Use Agreement, the parties agree that the Hospital will refrain from submitting PHI to ACS, and ACS will refrain from accepting PHI from the Hospital. Termination of this Agreement will not affect Hospital's participation in any other ACS programs.

14. 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.

15. No Warranty; Limitation of Liability.

a. Disclaimer of Warranty. To the maximum extent permitted by applicable law, ACS TQIP, the NTDB, and the services provided by ACS hereunder ("ACS TQIP Materials") are provided "as is" with all faults, and ACS disclaims any and all express or implied representations and warranties with respect to the ACS TQIP Materials, including any express or implied warranty of merchantability, fitness for a particular purpose, accuracy, non-infringement, or that the ACS TQIP materials will operate error free, uninterrupted or be free of viruses. The entire risk as to the selection, satisfaction quality and performance and use of ACS TQIP Materials shall be with Hospital.

b. Limitation of Liability. To the maximum extent permitted by applicable law, in no event shall ACS be liable for any indirect, special, incidental, consequential, punitive, or exemplary damages (including damages related to delays, loss of data, interruption of service or loss of use, business, revenue, or profits) in connection with this Agreement, use or inability to use the ACS TQIP Materials, under any legal theory, even if ACS has been advised of the possibility of such damages. Except as provided in the Business Associate and Data Use Agreement, in no event shall ACS be liable for any third party claim. Liability for damages shall be limited and/or excluded as provided in this Agreement, even if any exclusive remedy provided for in this Agreement fails of its essential purpose.

16. Miscellaneous.

a. Amendment. Any amendment to this Agreement must be in writing and signed by both of the parties.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

g. 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.

h. 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.

i. 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.

j. 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
Attn: Gay Vincent
633 North Saint Clair Street
Chicago, IL 60611
Fax: 312-202-5015

Natividad Medical Center
Attn: Dr. Gary Gray
1441 Constitution Blvd.
Salinas, CA 93912-1611
Fax: (831) 755-6254

k. Exclusion. ACS states that to the best of its knowledge it is not currently excluded from participating in any federal health care program.

l. Insurance. ACS agrees to maintain business liability insurance which ACS determines is commercially reasonable and sufficient to cover its obligations under this Agreement.

m. Access to Books and Records. If and to the extent applicable to ACS, for four (4) years after services are furnished pursuant to the Agreement, ACS shall retain, and shall allow the Comptroller General of the United States, the United States Department of Health and Human Services, and their duly authorized representatives, access to the Agreement and to such of ACS's books, documents, and records as are necessary to verify the nature and extent of the costs of the services rendered pursuant to the Agreement. If ACS provides services or a portion of services identified in the Agreement pursuant to a subcontract with an individual or organization that is related to ACS by control or common ownership and the services or portion of services provided pursuant to the subcontract has a value or cost of \$10,000.00 or more over a twelve (12) month period, ACS shall require the subcontractor in writing through the subcontract to retain and allow access to its records on the same terms and conditions as set forth herein. This Section shall be null and void to the extent Section 1861(v)(1)(I) of the Social Security Act, as amended, is not applicable to this Agreement.

Gay Vincent, Chief Financial Officer
American College of Surgeons

Date

County of Monterey, on behalf of Natividad Medical Center

By: _____
Gary R. Gray, DO, CEO

Date: _____

Approved as to Legal Form:

By: AB
Deputy County Counsel

Date: 12-1-15

Approved as to Fiscal Provisions:

By: [Signature]
Auditor/Controller

Date: 12-3-15

Exhibit A
Services Provided to the Hospital

Training and Education

1. Annual TQIP Conference. The annual fee paid by the Hospital includes the registration fee for two people to attend the in-person annual conference. Additional people may attend the in-person training at the registration cost set for each annual conference.
2. TQIP Training Activities. TQIP provides monthly online training activities in various formats. An unlimited number of individuals may access the online training at no additional cost.
3. Conference Calls/Web Conferences. ACS will have regular conference calls and/or web conferences to conduct training on relevant topics such as the use of TQIP data for performance improvement and data quality issues and to present report results to participants.

Data Accrual

1. The Hospital will have access to the following reports upon uploading data files:
 - a. Data Validation Reports
 - b. Frequency Submission Reports
2. ACS will monitor accrual rates and data quality to evaluate whether there are issues related to record submission. The Hospital will be notified of data issues through NTDB/TQIP Validator reports.

Clinical Performance Improvement Reports

The ACS TQIP has developed a set of reports for use by Hospital in support of Clinical Performance Improvement efforts. These reports will allow Hospital to view its data in summary and detail and to benchmark its results against all other participating hospitals. These reports include but are not limited to:

1. Data analysis tools that allow the Hospital to drill down into its own data
2. Annual Reports including
 - a. Risk-adjusted outcomes
 - b. Aggregate report on Hospital and patient characteristics
3. New Report Development as deemed appropriate
4. TQIP Participant Use File

Customer Service Support

ACS will supply customer service and technical support to the Hospital including phone and email support - timely response to questions; quality assurance and monitoring of data submission process; and help desk support.

Technical Services

1. ACS will maintain processes for data collection, validation, and other technical services. The data collection web site contains an interface module that handles the communication between the local sites (via Internet) and the central site. Through the central web site, ACS will provide the following capabilities:
 - a. Secured Firewall and VPN to prevent unauthorized intrusions
 - b. Data Protection by user account and password
 - c. Web based data submission
 - d. Standard XML data format
 - e. Local and central data validation
 - f. Data blinding to de-identify patients and medical centers by encrypting data based on Facility ID
 - g. Data monitoring to measure data accrual and volume
 - h. Online tool for reporting
 - i. Database to store transaction data

Exhibit B
Hospital Participation Requirements

1. Commitment from the Hospital's Trauma Medical Director or his/her designee to oversee ACS TQIP implementation and administration at the Hospital.
2. Participation of the Trauma Medical Director or his/her designee on semiannual conference calls.
3. Funding for the Trauma Medical Director or his/her designee to attend the TQIP annual conference. Annual fee to ACS does not include travel costs.

Data Collection by a Trained Trauma Registrar/Data Abstractor:

1. Hospital agrees to employ a qualified, dedicated registrar/abstractor to collect and submit data to the ACS TQIP. If Hospital uses an abstractor, all references to the registrar in the Exhibit B, and all obligations of the Hospital pertaining thereto, shall be read to extend and apply to the abstractor.
2. The Hospital will provide the registrar with:
 - a. Office space, adequate for protecting patient health information that may be available to the registrar;
 - b. Phone, fax, copier access;
 - c. Personal computer with access to the Internet (high-speed preferable); and
 - d. Necessary access to medical records and patient information (paper or electronic) for collection of ACS TQIP data elements.
3. The registrar must complete the ACS TQIP training course each year, and updates to the training materials as they occur.
4. The registrar must complete educational experiences and participate in the available web conferences.
5. Hospital agrees to provide funding (travel and accommodations) for the relevant staff to attend the TQIP annual conference.
6. In the event that the registrar is on extended leave or has chosen to leave the position during the program year, a backup registrar should be identified, trained, and be ready to assume the role of data collector.

Data Quality/Submission:

1. Maintain a trauma registry that is compliant with the National Trauma Data Standard (NTDS) and meets the current requirements of the NTDS. ACS does not supply the trauma registry or software required to establish and maintain the trauma registry.
2. Keep registry data submissions current with the most recent release of the National Trauma Data Standard data elements and inclusion criteria.
3. Provide data via the TQIP data submission process, in accordance with all inclusion criteria, data dictionary, validation and format requirements, and within ACS deadlines.
4. Maintain consistent and high quality data compliance, as evidenced by regular data monitoring. In the event there are ongoing and/or unaddressed data quality and accrual issues the Hospital may not receive TQIP reports. The Hospital will be notified at least two months in advance of the decision to not provide reports.
5. Make active use of all TQIP reports to continuously assess and improve quality of data provided to TQIP.
6. ACS TQIP will monitor data quality on an annual basis through data scrutiny and analysis, and use results of the monitoring to determine when an audit is needed.
 - a. The Hospital agrees that ACS will conduct inter-rater reliability audits of TQIP data remotely or onsite when necessary.
 - b. The Hospital agrees to host on-site and remote data audits by ACS TQIP personnel to assess the quality of data.
 - c. The date and time of the audit will be set upon mutual agreement by ACS and the Hospital.
 - d. If conducted remotely, it will be the responsibility of the Hospital to ensure the medical record is redacted prior to review.
7. If the Hospital's data show better than expected performance, the Hospital may, upon the ACS TQIP's request, be asked to share systems, strategies, and information with other participants in the ACS TQIP. (This sharing will not involve disclosure of identifiable patient information).
8. New measures may be introduced from time to time that will require new data elements, software updates, and additional training. These measures will be included in the NTDS data dictionary revision cycle. The Hospital must maintain an up to date trauma registry based on the NTDS data dictionary.

Exhibit C
Service Level Options

Selection of TQIP Program:

Select the program(s) that apply:

- ACS TQIP
 ACS Pediatric TQIP

Selection of Annual Discounts:

ACS will determine on an annual basis if Hospital qualifies to receive a discount(s).

5% Discount
Hospital will receive an annual discount of 5% each year if they participate in two (2) TQIP Programs (TQIP, Pediatric TQIP, or TQIP Collaborative)

10% Discount
Hospital will receive an annual discount of 10% each year if they participate in three (3) TQIP Programs (TQIP, Pediatric TQIP, and TQIP Collaborative)

Collaborative Participation

Name of Collaborative: Click here to enter text.

Your Hospital must be part of an ACS TQIP-recognized Collaborative to receive a discount.

Annual Fees:

The Hospital agrees to pay to ACS an annual fee for participation in ACS TQIP. Detailed below is a current Pricing Guide of ACS TQIP options as of July 1, 2015.

Current Annual Fees:

Adult TQIP Only	\$9,000.00
Pediatric TQIP Only	\$9,000.00
Adult TQIP combined with Pediatric TQIP (5% discount included)	\$17,100.00
Adult TQIP in Collaborative (5% discount included)	\$8,550.00
Adult TQIP combined with Pediatric TQIP in a Collaborative (10% discount included)	\$16,200.00

FOR TQIP STAFF TO COMPLETE:

Hospital participates in following programs:

- ACS TQIP
- ACS Pediatric TQIP
- TQIP State Collaborative

Total Discount Percent Applied _____

Total Fee \$9,000.00 for year one of the Agreement.

BUSINESS ASSOCIATE AND DATA USE AGREEMENT

NAME OF COVERED ENTITY: County of Monterey on behalf of Natividad Medical Center

COVERED ENTITY FEIN/TAX ID: 94-600524

COVERED ENTITY ADDRESS: 1441 Constitution Blvd., Salinas CA 93906

This **Business Associate and Data Use Agreement** ("Agreement") is effective as of the date signed by both parties ("Effective Date") between County of Monterey on behalf of Natividad Medical Center ("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 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 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. Covered Entity will provide ACS with a copy of its Notice of Privacy Practices upon request.
- 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 (NMC)
Attn: Contracts Division
1441 Constitution Blvd.
Salinas, CA 93912-1611
Fax # (831) 757-2592

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

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

Date

Gary R. Gray, DO, CEO

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

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

Date