

## HOSPITAL PARTICIPATION AGREEMENT INCLUDING BUSINESS ASSOCIATE AND DATA USE AGREEMENTS

NAME OF HOSPITAL: Natividad Medical Center, County of Monterey  
HOSPITAL FEIN/TAX ID: 94-6000524  
HOSPITAL ADDRESS: 1441 Constitution Blvd.  
Salinas, Ca. 93906

This **Hospital Participation Agreement including Business Associate and Data Use Agreements** ("Agreement") is effective as of the date signed by both parties ("Effective Date") between Natividad Medical Center ("NMC"), a general acute care teaching hospital wholly owned and operated by the County of Monterey, which is a political subdivision of the State of California ("Hospital") and the American College of Surgeons ("ACS") and shall continue through the end of the "Participation Period" as defined in Section 1 below.

WHEREAS, Hospital desires to participate in the ACS National Surgical Quality Improvement Program ("ACS NSQIP") and ACS desires to receive data from 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 Hospital's first Surgical Clinical Reviewer ("SCR") participates in the training session and will continue for the length of time described on Exhibit A, attached to and made a part of this Agreement. ACS will send Hospital a letter confirming the commencement of the Participation Period and its end date after the SCR has registered and been confirmed for the SCR training session.
- 2. Options.** The ACS NSQIP has established participation levels (the "Option(s)"), each of which has associated data contribution requirements and fees. Hospital has chosen, and ACS has confirmed, the Option indicated on Exhibit A ("Hospital's Option"). Hospital will continue participation in the chosen Option through the Participation Period unless ACS and Hospital mutually agree in writing to change the Hospital's Option and amend this Agreement accordingly. ACS will consider the timing of data reporting cycles to determine when participating hospitals will have an opportunity to select a different Option.
- 3. Contribution of Data.** Hospital agrees to contribute certain data (the "ACS NSQIP Data") to a proprietary database established by the ACS (the "ACS NSQIP Database"). Hospital must submit its ACS NSQIP Data in accordance with the data reliability standards established by ACS NSQIP. Hospital agrees to contribute a set number of cases based on the minimum data contribution requirements for Hospital's Option as established by ACS NSQIP and generally described on Exhibit B. Hospital will submit data in the format as required by ACS NSQIP via the official ACS NSQIP web-based data collection system ("Workstation") with standardized fields as developed by ACS and/or ACS authorized vendor(s). Hospital agrees to use an ACS authorized vendor and ACS will not be required to accept data from any other vendor. 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 13.b.iv. below).

4. Fees. Hospital agrees to pay to ACS an annual fee for participation in the ACS NSQIP for the Participation Period described on Exhibit A. Hospital shall pay additional fees as described in Section 10, Data Collectors, and Section 12, Audits, as applicable.
5. Payment. Hospital will pay the annual fee for participation for each year of the Participation Period, in advance. ACS will provide Hospital with an invoice for the first year of the Participation Period upon receipt of a fully executed Agreement. Thereafter, ACS will provide an invoice thirty (30) days prior to the anniversary date of the Participation Period. Payment is due in accordance with the County of Monterey Agreement for Services ("County Agreement").
6. Services Provided to Hospital. ACS will provide to Hospital the services described on Exhibit C.
7. Hospital Requirements. Hospital will continuously comply with the participation requirements described on Exhibit D and subject to change from time to time.
8. Access to and Use of Data. Hospital will have continuous access to Hospital's own ACS NSQIP Data. 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 Hospital a limited, non-exclusive, revocable license to utilize these non-risk-adjusted ACS NSQIP Data for appropriate internal purposes only. ACS NSQIP will provide reports to Hospital from time to time, which will contain risk-adjusted ACS NSQIP Data. ACS hereby grants Hospital a non-exclusive license to use the risk-adjusted data for appropriate internal and external purposes.
9. Confidentiality of Hospital's Identity. ACS will not release Hospital's ACS NSQIP Data in any format or circumstance that identifies 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 specifically authorized by Hospital. If any legal demand for Hospital's ACS NSQIP Data is made upon ACS, ACS will promptly notify Hospital so that Hospital may, at its option, challenge the validity of the legal process. The provisions of this section shall survive any termination or expiration of this Agreement.
10. Data Collectors. Hospital agrees to dedicate the required number of data collectors as determined by Hospital's surgical volume. Replacement and backup SCRs and additional staff may attend the SCR training for a fee of \$2,500 per individual trained.
11. Access to Workstation. Hospital acknowledges and agrees that it is responsible for controlling access to Hospital's own data and Hospital's Workstation at all times. Hospital will provide ACS NSQIP with a current and up to date list of authorized Hospital users with a need to access the Workstation. Hospital agrees to promptly notify ACS NSQIP of any changes to its list of authorized users, including additions and deletions to the list of authorized users.
12. 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 and/or remote audits of Hospital's data and collection procedures. ACS will provide at least ten (10) business days notice of an on-site audit. To the extent medical records are needed to conduct the audit, ACS will request and Hospital will provide only the minimum necessary portions of the record needed for the audit. Additional audits may be required by ACS NSQIP or requested by Hospital for an additional fee of \$3,500 per audit.

13. Business Associate and Data Use Provisions. ACS NSQIP requires 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, including the Administrative Simplification provisions, the Secretary of Health and Human Services regulation modifications for 45 CFR Parts 160 and 164, the HIPAA Privacy Rule ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH") and the State of California Confidentiality of Medical Information Act ("CMIA"), California Civil Code Section 56 *et seq.*, Senate Bill 541, enacted September 30, 2008, and Assembly Bill 211, enacted September 30, 2008 and the regulations issued thereunder (collectively, the "HIPAA and CMIA regulations"). The parties acknowledge that California law may include provisions more stringent and more protective of the confidentiality of health information than the provisions of HIPAA. These Uses and Disclosures are for purposes of conducting data analyses that relate to 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 and CMIA Regulations require 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 13 constitute the equivalent of a Business Associate Agreement and a Data Use Agreement.

- 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 and CMIA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of 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 Hospital to ACS or an agent or subcontractor of ACS, or created by ACS or its agent or subcontractor on behalf of Hospital. The parties agree that ACS is a Business Associate and Hospital is a Covered Entity under the terms of the HIPAA Regulations. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, as amended, the HIPAA Privacy Rule shall control. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of CMIA, California law shall control. Where provisions of this Agreement are different than those mandated in HIPAA and CMIA, but nonetheless are permitted by HIPAA and CMIA, the provisions of this Agreement shall control.
- 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 and CMIA Regulations if done by Hospital. Without limiting the generality of the foregoing, 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 13.c.vii. and 13.e. below.
- v. For data aggregation services, if to be provided by ACS for the Health Care Operations of Hospital. For purposes of this Agreement, data aggregation services means the combining of PHI by Business Associate with the PHI received by ACS in its capacity as a Business Associate of another Covered Entity, to permit data analyses that relate to the Health Care Operations of the respective Covered Entities.

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), and CMIA concerning Disclosures in the public interest, or other permissible Uses or Disclosures by a Business Associate as set forth in the HIPAA and CMIA 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) and CMIA, 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) and CMIA.
- 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 and CMIA 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 and CMIA Regulations if done by Hospital. Consistent with the HIPAA and CMIA 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 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 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 within 5 days.
- iv. ACS agrees to ensure that any agent, including a subcontractor, to whom it provides or who accesses 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 13.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 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 Hospital's compliance with the HIPAA Regulations.
- vi. If PHI provided to ACS 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 and CMIA 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 Hospital may reasonably direct or agree to pursuant to 45 CFR 164.526 and CMIA. 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 and CMIA. 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 and CMIA. 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 and CMIA 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.

- x. In the event of an unauthorized Use or Disclosure that constitutes a Breach of Unsecured PHI (as defined by the HITECH Act), ACS will notify Hospital without unreasonable delay but in no event later than five (5) calendar days following the Discovery of such Breach. 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).
- 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 13.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) and CMIA;
  - ii. will not Use or further Disclose the Limited Data Set in a manner that would violate the HIPAA and CMIA Regulations if done by 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 Hospital as required by 45 CFR 164.314 and CMIA;
  - v. will promptly report to 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 within five (5) calendar days of discovering such improper access, use or disclosure. In addition, ACS agrees to mitigate, to the extent practicable, any harmful effect that is known to ACS of a use, disclosure, or access of Protected Health Information by ACS in violation of the requirements of this agreement;
  - 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 Hospital.
- i. 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 CMIA and any other applicable provisions of the HIPAA Regulations. Hospital will provide ACS with a copy of its Notice of Privacy Practices upon request.
  - ii. Hospital shall notify ACS of any limitation(s) in Hospital's Notice of Privacy Practices, to the extent that such limitation may affect ACS's Use or Disclosure of PHI.
  - iii. To Hospital's knowledge, as of the Effective Date, all Disclosures of PHI made to ACS are permissible Disclosures under the HIPAA and CMIA Regulations, and no Individual has restricted Disclosure so as to make the

Disclosure to ACS impermissible. Hospital will notify ACS of any restriction on the Use or Disclosure of PHI that Hospital has agreed to in accordance with the HIPAA Regulations, 45 CFR 164.522, and CMIA if such restriction affects ACS's Use or Disclosure of PHI.

- iv. Hospital will not ask ACS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA and CMIA Regulations if undertaken by Hospital; provided that 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) and CMIA.

14. 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 Hospital that it receives or generates in connection with this Agreement and that Hospital designates as confidential. ACS will use such information solely to carry out this Agreement and will not disclose such information without Hospital's prior written approval or as Required By Law. The provisions of this section shall survive any termination or expiration of this Agreement.

15. Use of Name. Neither ACS nor 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 Hospital in lists of participants in the ACS NSQIP, and Hospital may state that Hospital participates in the ACS NSQIP.

16. Termination.

(a) ACS reserves the right to terminate this Agreement upon thirty (30) days prior written notice to Hospital, if Hospital materially fails to fulfill the terms of the Agreement or materially violates its conditions, in which case ACS will not refund fees previously paid by Hospital. Hospital may terminate this Agreement at any time, provided that Hospital will be obligated to pay (to the extent Hospital has not already paid) the fees calculated as follows: (i) all fees applicable for the then-current Participation Period if the Participation Period is one (1) year; or (ii) if the Participation Period is three (3) years, all fees applicable for the then-current one (1) year period calculated without application of any multi-year discount, plus the amount of the multi-year discount for prior years during the then-current three-year term.

(b) If ACS is in material breach of this Agreement and fails to correct or cure such breach within thirty (30) days following written notice from Hospital, then Hospital may terminate this Agreement. ACS may also terminate this Agreement prior to the end of a Participation Period if ACS suspends data collection. In either 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.

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

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

19. 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.

20. No Warranty; Limitation of Liability; Indemnification.

- a. Disclaimer of Warranty. To the maximum extent permitted by applicable law, ACS NSQIP and the services provided by ACS hereunder ("ACS NSQIP 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 NSQIP Materials, including any express or implied warranty of merchantability, fitness for a particular purpose, accuracy, non-infringement, or that the ACS NSQIP 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 NSQIP 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 NSQIP Materials, under any legal theory, even if ACS has been advised of the possibility of such damages. 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.
- c. 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 Section 13 of 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.

21. Miscellaneous.

a. Regulatory References. A reference in this Agreement to a section in the HIPAA and CMIA 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 parties to comply with the requirements of federal and applicable state law and regulations including the HIPAA and CMIA Regulations and the HITECH Act of 2009. 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 and CMIA Regulations.

c. Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Hospital and ACS to comply with HIPAA and CMIA 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 and the County Agreement constitute 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. Intentionally omitted.

h. Third Party Beneficiaries. ACS and 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. Insurance. ACS Agrees to maintain insurance that ACS determines in its sole discretion is reasonable.

m. 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	Hospital:
Attn: Gay Vincent	
633 North Saint Clair Street	
Chicago, IL 60611	
Fax: 312-202-5025	

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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**

Henry Weis CEO

12/10/12

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



12/10/12

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

**Date**



**EXHIBIT A  
SERVICE LEVEL OPTIONS**

NAME OF HOSPITAL: Natividad Medical Center  
HOSPITAL ADDRESS: 1441 Constitution Blvd  
Salinas, CA 93906

**SELECTION OF TERM FOR PARTICIPATION PERIOD:**

The "Participation Period" is defined as the period beginning on the first day of the month that Hospital's first Surgical Clinical Reviewer ("SCR") participates in the training session and will continue for the length of time described on Exhibit A, attached to and made a part of this Agreement. ACS will send Hospital a letter confirming the commencement of the Participation Period and its end date after the SCR has registered and been confirmed for the SCR training session.

**Select the term for the Participation Period:**

- Twelve (12) consecutive months**
- Thirty-six (36) consecutive months**

**SELECTION OF HOSPITAL OPTION:**

The ACS NSQIP has established participation levels (the "Option(s)"), each of which has associated data contribution requirements and fees. Hospital has chosen, and ACS has confirmed, the Option indicated on Exhibit A ("Hospital's Option"). Hospital will continue participation in the chosen Option through the Participation Period unless ACS and Hospital mutually agree in writing to change the Hospital's Option and amend this Agreement accordingly. ACS will consider the timing of data reporting cycles to determine when participating hospitals will have an opportunity to select a different Option.

**Select one of the following as Hospital's Option:**

- ACS NSQIP Essentials**
  - General & Vascular Surgery**
  - Multispecialty** (Must also complete and attach the Multispecialty Case Volume and SCR Worksheet)
- ACS NSQIP Small & Rural**
  - Rural** (Hospital zip code falls under Rural Urban Commuter Area (RUCA) data codes 7.0 through 10.6.)
  - Small** (Hospital performs fewer than 1680 +/- 5% cases per year.)

- ACS NSQIP Procedure Targeted**
  - General & Vascular Surgery**
  - Multispecialty**
- ACS NSQIP Measures**
- ACS NSQIP Pediatric**

**SELECTION OF ANNUAL FEE:**

The Hospital agrees to pay to ACS an annual fee for participation in the ACS NSQIP for the Participation Period. Detailed below is a current Pricing Guide to the ACS NSQIP Options. The annual fee that applies to the ACS NSQIP Option of choice will be fixed for the term of the Participation Period as selected above. Additional fees may apply as described in Section 10, Data Collectors, and Section 12, Audits.

**Select the Annual Fee that applies to the ACS NSQIP Option of choice:**

- \$27,000 ACS NSQIP Essentials**
- \$10,000 ACS NSQIP Small & Rural**
- \$29,000 ACS NSQIP Procedure Targeted**
- \$15,000 ACS NSQIP Measures**
- \$29,000 ACS NSQIP Pediatric**

**SELECTION OF ANNUAL DISCOUNTS:**

ACS will determine on an annual basis if Hospital qualifies to receive a discount(s) based on certain criteria. Small and Rural Option and Measures Option participants are not eligible for any discounts.

**Select the 3 Year Contract Discount if a 3-year term for the Participation Period has been selected above:**

- (\$1,500) 3 Year Contract Discount**
  - Hospital will receive an annual discount of \$1,500, i.e. discounted each year if a 3-year term Participation Period selected above.

Hospitals are eligible for either a System Discount or a Collaborative Discount, but not both. Small and Rural Option and Measures Option hospitals that are part of a system may be counted toward the system volume threshold requirements so that larger hospitals in the system may qualify for a System Discount.

Select either **System Discount** or **Collaborative Discount**:

**(\$3,500) System Discount**

**Name of System:** \_\_\_\_\_

**System Discount:**

- Must meet the ACS definition of a "System." A "System" is defined as two or more hospitals that are owned, leased, or contract managed by a central organization.
- 5 or more hospitals from a system must enroll in ACS NSQIP in order for any one of them to receive a system discount or 100% of the hospital system, if less than 5 hospitals in a system. Discount is \$3,500 per hospital per year.
- For any hospital that participates in the ACS NSQIP prior to their system meeting the system discount requirements, that hospital will be entitled to the discount at the time of their next contract (or if on a three year contract, at the time of their next annual invoice) once their system meets the threshold requirements.
- Hospitals in a system may participate in different options.

**(\$3,500) Collaborative Discount**

**Name of Collaborative** \_\_\_\_\_

**Collaborative Discount:**

- Hospital must be part of an ACS NSQIP recognized collaborative. The definition of an ACS NSQIP "recognized collaborative" includes the following:
  - Must have a formal data sharing agreement signed between the participating hospitals and the ACS NSQIP
  - Must hold quarterly meetings and produce meeting minutes
  - Focused on surgical quality improvement activities
- Hospitals in a collaborative may participate in different options.

**(\$2,000) Pediatric Discount**

**Name of Adult Affiliate** \_\_\_\_\_

**Pediatric Discount:**

- Available only to Pediatric hospitals.
- Pediatric hospitals are eligible for an annual discount if their adult affiliate hospital also participates in ACS NSQIP Classic, Essentials, Small and Rural, Procedure Targeted, or Measures.

**EXHIBIT B  
ACS NSQIP Options**

	<b>Classic</b>	<b>Essentials</b>	<b>Small &amp; Rural</b>	<b>Procedure Targeted</b>	<b>Pediatric</b>	<b>Measures</b>
<b>Who is Eligible</b>	Any hospital	Any hospital	Small and rural hospitals  (Small defined as performing fewer than 1680 +/- 5% cases per year. Rural defined as RUCA data codes 7.0 through 10.6.)	Any hospital	Freestanding General Acute Care Children's Hospital  Children's Hospital within Larger Hospital  Specialty Children's Hospital  General Acute Care Hospital with Pediatric Wing	Any hospital
<b>Best Suited For</b>	Hospitals wanting additional data for research purposes	Hospitals wanting to collect only the essential elements for QI Purposes	Small and rural hospitals	Larger hospitals; Those w/ CPT codes available within the hospital	Hospitals with a Pediatric population	Hospitals with limited resources and need to focus on QI efforts
<b>Number of Variables</b>	Approximately 69 "Clinical" Variables	Approximately 46 "Clinical" Variables  (Subset of Classic)	Approximately 46 "Clinical" Variables  (Same as Essentials)	"Core" set of approximately 46 "Clinical" Variables + Procedure specific variables ("Core" set is the same as Essentials)	Approximately 94 "Clinical" Variables	Approximately 25 "Clinical" Variables
<b>Versions Available</b>	General/Vascular Multispecialty	General/Vascular Multispecialty	Multispecialty	General/Vascular Multispecialty	Multispecialty	Multispecialty
<b>Case Volume Requirements</b>	General/Vascular = 1680 cases per year (or all cases if less than 1680)  Multispecialty = 20% total case volume by specialty (minimum 1680 cases or all cases if less than 1680)	General/Vascular = 1680 cases per year (or all cases if less than 1680)  Multispecialty = 20% total case volume by specialty (minimum 1680 cases or all cases if less than 1680)	Maximum = 1680 cases per year	Minimum = 1680 cases per year  (Exact volume dependent on the # of targeted procedures selected and hospital volume for each of these procedures)	Maximum = 1400 cases per year	Maximum = 840 cases per year
<b>Sampling</b>	General/Vascular = 40 cases per 8 day cycle  Multispecialty = May be more than 40 cases per 8 day cycle - dependent on volume	General/Vascular = 40 cases per 8 day cycle  Multispecialty = May be more than 40 cases per 8 day cycle - dependent on volume	All cases (100% capture)	15 "Core Cases" per 8 day cycle (use NSQIP standard sampling methodology to select cases)  25 "Procedure Targeted" Cases per 8 day cycle (or more if additional FTEs available)	Multispecialty = 35 cases per 8 day cycle	Multispecialty = 20 cases per 8 day cycle
<b>FTE Requirements</b>	1 FTE Minimum  May be more for Multispecialty-use formula: # cases required/1680 = # FTE required	1 FTE Minimum  May be more for Multispecialty-use formula: # cases required/1680 = # FTE required	¼ FTE for up to 400 cases ½ FTE for up to 800 cases ¾ FTE for up to 1200 cases 1 FTE for up to 1680 cases	1 FTE Minimum  May be more if hospital chooses to collect more than 1,050 "Targeted" procedures per year	1 FTE Minimum	¾ FTE Minimum

Effective as of May 2012

## **EXHIBIT C SERVICES PROVIDED TO HOSPITAL**

### **A. SCR Training, Education & Support**

The ACS NSQIP will provide training, education, and support to the Surgical Clinical Reviewers (SCRs):

- **Initial Training Sessions for new SCRs**
- **SCR Conference Calls**
- **Clinical Support and Communications**

In addition, the ACS NSQIP will provide:

- **SCR Job Description and Hiring Qualifications Document**

### **B. Monitoring of Data Accrual Rates and Data Sampling Methodologies**

The ACS NSQIP will monitor accrual rates and data sampling methodologies and make recommendations for Hospitals that are not meeting the Program requirements. These Hospitals will then be contacted directly to discern the reason for any discrepancies and to discuss a plan of action for correcting them.

### **C. Clinical Performance Improvement Reports**

The ACS NSQIP has developed a set of reports for use by the Hospitals in support of their Clinical Performance Improvement efforts. These reports will allow Hospitals to view their surgical data in summary and detail and to benchmark their results against other participation hospitals. These reports include:

- **Non-Risk Adjusted Online Reports & Benchmarking Tools**
- **Risk Adjusted Semiannual Reports**

### **D. IT and Customer Service Support**

The ACS NSQIP will supply customer service and technical support to Hospitals including the set up of new Hospitals; phone and email support; quality assurance and monitoring of software performance; occasional and reasonable ad-hoc report generation for Hospitals; help desk support for SCRs; software set-up and support for workstation software; and software and application maintenance and enhancement.

### **E. Software**

The ACS NSQIP Workstation and XML Uploader (a data automation schema) are available to Hospitals to increase productivity of data collection.

## **EXHIBIT D HOSPITAL PARTICIPATION REQUIREMENTS**

### **Requirements for a Hospital's participation in the ACS NSQIP:**

#### **A. ACS NSQIP Program Administration and Oversight at the Hospital:**

- Commitment from the Hospital's Chief of Surgery or delegated surgeon to serve as Surgeon Champion (SC) and to oversee ACS NSQIP implementation and administration at the Hospital.
- Participation of the SC on program conference calls.
- Funding for the SC or his/her designee to attend a national ACS NSQIP meeting once per year.

#### **B. Data Collection by a Trained Surgical Clinical Reviewer (SCR):**

- Hospital agrees to hire a qualified, dedicated SCR to collect and submit data to the ACS NSQIP.
- This SCR will be dedicated to the ACS NSQIP and will be provided with necessary access to medical records and patient information (paper or electronic) for collection of ACS NSQIP data elements.
- The SCR must successfully complete the ACS NSQIP training program, any required or associated exams, and participate in on-going training, conferences, and conference calls.
- Hospital agrees to provide funding for the SCR to attend a national ACS NSQIP meeting once per year.
- In the event that the SCR is on extended leave or has chosen to leave the position during the program year, Hospital is expected to identify a back-up SCR ready to participate in training to assume the role of data collector.

#### **C. Payment of Annual Fee:**

- An annual fee paid to the American College of Surgeons will cover the cost of participating in ACS NSQIP:
  - ACS NSQIP website
  - Web-based Workstation
  - XML Uploader
  - Data verification and encryption
  - Data analysis
  - Report production
  - Inter-rater reliability determination and audits
  - Training and support for one SCR
  - On-line Benchmarking
  - Semiannual Report



**D. Data Quality/Reporting:**

- The implementation of the data acquisition and transmission protocol as outlined in the ACS NSQIP Operation Manual. This includes:
  - Meeting the data accrual requirements as described in the ACS NSQIP Hospital Participation Agreement, Section 3 "Contribution of Data".
  - Maintaining high quality of data collection.
  - Obtaining complete 30-day follow-up on all participating patients through the generation of a 30-day follow-up letter and/or phone calls to patients and periodic death searches of public records.
  - Facilitating and hosting Inter-rater Reliability Audits by ACS NSQIP personnel to assess the quality of data, as described below.

Note: The ACS NSQIP will monitor data accrual. Failure to meet data collection requirements may result in the exclusion of the data collected by the Hospital from the semiannual reports and may also result in the termination of the Hospital from the ACS NSQIP.

County of Monterey  
General Services- Contracts/Purchasing Division  
JUSTIFICATION OF SOLE SOURCE/SOLE BRAND REQUEST

Purchase Requisition Number \_\_\_\_\_ Date 9/4/2012

Description of Item: ACS- NSQIP (American College of Surgeons - National Surgical Quality Improvement Program)

1. Please indicate the following:

Procurement:  Goods  
 Services

- (Check One)
- Sole Source: Item is available from one source only. Item is a one-of-a kind and is not sold through distributors. Manufacturer is exclusive distributor.
- Sole Brand: Various sources can supply the specified model and brand and competitive bids will be solicited for the requested brand only. Meets form, fit and function- nothing else will do.

Note: Sole Source/Sole Brand Requests are not maintained as a standing request. Each request is for a single one-time purchase only.

2. Vendor Selection:

Preferred Vendor  
 Sole Source

Vendor Name: ACS- NSQIP  
Address: 633 N. Saint Clair St. City Chicago State: IL 60611-  
Phone Number: (312) 202-5000 Fax: (312) 202-621-4111 324  
Contact Person: Gina M. Pope Title: Business Development Representative  
Federal Employer #: \_\_\_\_\_

3. Provide a brief description of the goods/services to be purchased and why this purchase is being proposed under a sole source acquisition.

a) Why were product and/or vendor chosen?

See attached

- b) What are the unique performance features of the product/brand requested that are not available in any other product/brand? For Services: what unique qualifications, rights, and licenses does the vendor possess to qualify as a sole source/brand request?

*see attached*

- c) Why are these specific features/qualifications required?

*see attached*

- d) What other products/services have been examined and/or rejected?

*see attached*

- e) Why are other sources providing like goods or services unacceptable (please give a full meaningful explanation)?

*see attached*

- f) What are the unique performance features REQUIRED (not merely preferred), and how would your requirement be inhibited without this particular item or service?

*see attached*

- g) Estimated Costs:

*\$ 30,000*

4. Is there an unusual or compelling urgency associated with this project?

No

Yes (Please describe)

*see attached*

**THE FOLLOWING TO BE COMPLETED BY THE REQUESTOR**

I hereby certify that:

1. I am an approved department representative, and am aware of the County's requirements for competitive bidding, as well as the criteria for justification for sole source/brand purchasing.
2. I have gathered the required technical information and have made a concentrated effort to review comparable and/or equal equipment.
3. The information contained herein is complete and accurate.
4. There is justification for sole source/brand purchasing noted above as it meets the County's criteria.
5. A sole source/brand purchase in this case would withstand a possible audit or a vendor's protest.

Requestors Signature

*Jane A. Dundy*

Date

*9/4/2012*

Authorized Signature by Department Head

*[Signature]*

Date

*9/4/2012*

## **Sole Source Justification – ASC NSQIP (American College of Surgeons – National Surgical Quality Improvement Project)**

### **3a. Why were products and/or vendor chosen?**

- American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®). ACS NSQIP is the leading nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care in the private sector. ACS NSQIP has the tools, training, customization options and, most importantly, data, to keep Natividad Medical Center (NMC) ahead of the curve.

### **b. Unique performance features/qualifications?**

ACS-NSQIP is the industry "gold standard" for surgical quality data. Utilizing this database program will result in:

- **Fewer complications.** For patients at Surrey Memorial Hospital in Vancouver, British Columbia, the rate of surgical site infections after breast surgery dropped significantly. An estimated 75 infections were averted over the course of two years.
- **Better outcomes.** Eighty-two percent of ACS NSQIP hospitals saw improvement in postoperative morbidity levels and 66 percent improved mortality levels<sup>2</sup>.
- **Shorter hospital stays.** At Decatur General Hospital in Decatur, Ala., the hospital length of stay for patients with urinary tract infections (UTI) was twice as long as for patients without UTI at the beginning of ACS NSQIP implementation. Within one year, length of stay was the same for patients whether or not they had UTI, and the rate of post-surgical UTI fell from 3.1 percent to 0.8 percent.
- The American College of Surgeons (ACS) and CMS are working to allow ACS NSQIP hospitals to voluntarily report their outcomes on the publicly accessible Hospital Compare website. Because ACS NSQIP is based on the best available data – clinical, risk- and case-mix-adjusted, nationally benchmarked and audited 30-day patient outcomes – it provides a more accurate look at surgical quality than many other public measures, which are based on administrative data or compliance with process measures.

### **c. Why are the Specific features/qualifications required?**

Payors, including Medicare, increasingly refuse to pay for treating complications deemed preventable, such as surgical site infections. A growing movement aims to tie reimbursements to outcomes – and publicly report the results. NMC needs accurate surgical quality data to reduce complications.

#### **New CMS Measure: Participation in a General Surgery Registry**

Recently, the Centers for Medicare and Medicaid Services (CMS) announced a new measure to encourage participation in a general surgery registry and expressed its intention to move toward reporting based on clinical data and outcome measures. According to the rule announced in August 2011, hospitals will report their participation "in a Systematic Clinical Database Registry for General Surgery, in the Hospital IQR Program beginning with the FY 2014 payment determination."

### **d. What other products have been examined or rejected?**

None exist.

### **e. Why are other sources unacceptable?**

No other quality product exists that encompasses across multiple specialties.

### **f. What features are required?**

NMC needs a database that provides with clinical, risk- and case-mix-adjusted, nationally benchmarked and audited 30-day patient outcome data. ASC-NSIP provides a more accurate look at surgical quality than many other public measures, which are based on administrative data or compliance with process measures.

### **g. estimated costs:**

See exhibit A of proposal/agreement.

#### 4. Unusual/compelling urgency?

- Yes -- there is a growing movement with all payers to tie reimbursement to outcomes.
- Will satisfy Centers for Medicare and Medicaid Services surgical quality measure (NQF #0493) to be implemented in 2014, "Participation in a Systematic Clinical Database Registry for General Surgery."



**Telephone:** 831-783-2502 **Mobile:** 1

**Attachments:** 2011 SSAE 16 ISAE 3402 Proof Letter.pdf ACS Local Workstation Installation Manual v1.0.pdf ACS NSQIP IT FAQs.pdf

\*\* Target Resolution Date for Work Orders are estimates only. Actual completion time may depend on equipment/resource availability.



November 18, 2011

To Whom It May Concern:

Please accept this letter as confirmation that Savvis Communications Corporation has participated in a SSAE16 Type II Examination (SOC1) for the period of: October 1, 2010 – September 30, 2011. The examination included a review of our Network and Hosting Services (excluding VPCD), including global private network, colocation and managed hosting services. The report addresses internal operational controls to support the Atlanta (AT1), Boston (BO1, BO2, BO3), Chicago (CH3, CH4), Washington, D.C. (DC2, DC3, DC4), Dallas (DL1, DL2), Seattle (SE2), Santa Clara (SC4, SC5, SC8, SC9), New Jersey (NJ1, NJ2, NJ2x, NJ3), Los Angeles (LA1), Orange County (OC2), St. Louis (SL1), Slough (LO1), London (LO4), Reading (LO6), Singapore (SG8), Montreal (MR1), Toronto (TR1), Vancouver (VC1) and Tokyo (TY6) IDCs.

The following control objectives were reviewed for the 2011 SSAE16 reporting period:

**Service Delivery**

- Controls provide reasonable assurance that new installations and changes are fulfilled according to the customer's specifications.

**Support Services**

- Controls provide reasonable assurance that customer production systems are monitored and supported to help ensure availability and timely problem resolution.

**Physical Security – IDC Infrastructure**

- Controls provide reasonable assurance that physical access to Savvis IDCs, systems and network equipment, and storage media is limited to authorized individuals.

**Facility and Environmental Protection**

- Controls provide reasonable assurance that Savvis facilities housing customer equipment and support operations are designed and monitored to reduce the risk of environmental threats (e.g., power loss, fire, flooding).

**Managed Security Services**

- Controls provide reasonable assurance that security services provided to the customer, as contracted, are managed and administered appropriately.

**Information Security – IP Network (Customer Facing)**

- Controls provide reasonable assurance that access to network devices are administered and configured with appropriate security.
- Controls provide reasonable assurance that network events are being identified, tracked, and monitored.
- Controls provide reasonable assurance that network devices are maintained to address the latest security and operational risks, and this maintenance is managed so that network availability is minimally impacted.

- Controls provide reasonable assurance that network availability is monitored, documented, and communicated.
- Controls provide reasonable assurance that all critical Savvis network systems are backed up where appropriate and recoverable.

#### **Information Security – Corporate Systems and Network**

- Controls provide reasonable assurance that corporate devices and critical systems are configured with appropriate security.
- Controls provide reasonable assurance that critical system events are identified and tracked.
- Controls provide reasonable assurance that firewall availability is documented and implemented for all corporate production zones.
- Controls provide reasonable assurance that all critical Savvis firewall components are backed up where appropriate and recoverable.

#### **Global Change Management**

- Controls provide reasonable assurance that changes and enhancements to the production systems are properly authorized and approved to help ensure minimal impact to Savvis customers and production systems.

#### **Managed Storage**

- Controls provide reasonable assurance that storage services provided to the customer, are monitored to determine the security and availability of customer data.

#### **Managed Backup**

- Controls provide reasonable assurance that backup services provided to the customer, are monitored to determine the security and completion of customer backups.

#### **Managed Hosting**

- Controls provide reasonable assurance that managed customer servers are configured and administered with appropriate security.
- Controls provide reasonable assurance that managed customer servers are monitored and maintained to address operational risks in a timely manner. Monitoring and maintenance are performed to ensure maximum uptime for managed customer servers.

The 2011 SSAE16 report was prepared for Savvis, the users of the services and the independent auditors of those users; it is not designed for purposes of marketing Savvis' services to prospective Savvis customers.

Sincerely,



Jeff Von Deylen  
Senior Vice President, Global Operations



## ACS LOCAL WORKSTATION INSTALLATION GUIDE

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Installation Process of ACS Local Workstation.....	3
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## Introduction

The purpose of this guide is to provide a detailed description of the installation steps for the ACS Local Workstation tool. This tool was designed to be used in the event a hospital could not use the enhanced Web Based Workstation tool. It can be downloaded and saved onto your computer to ensure successful and efficient data entry at your hospital. The Local Workstation installation package can be downloaded by visiting: <https://acslocalworkstation.outcome.com/app/download.html>

## Installation Requirements

The following requirements need to be met prior to initiating the installation of the ACS Local Workstation:

- Operating System: Microsoft Windows XP, Vista, 7
- 100 MB available hard disk space
- 1 GB RAM
- Microsoft Internet Explorer 6 or higher with JavaScript enabled
- Java Runtime Environment 6 or higher
- Adobe Flash Player 9 or higher
- Internet Connection: Broadband (512 Kb/s or greater)
- A centrally located install of MS SQL Server 2005 or 2008 (Express or Standard Edition)
- You will need Administrative rights to your computer in order to successfully complete the installation

## Database Setup prior to installation

- A centrally located install of MS SQL Server 2005 or 2008 (Express or Standard Edition) (NOTE: ACS NSQIP strongly recommends this install be in a centrally accessible location on your hospital's network. SQL Server should be installed on a central machine so that any computer in the hospital network that has a copy of the ACS Local Workstation software can access that database. In addition, installation on a dedicated machine improves performance and maintenance (backup). Installing the database locally on an SCR's computer can create connectivity problems.
- The administrator will need to create a new database instance and login with DDL and DML privileges for the ACS Program in MS SQL Server.
- Network connectivity should be enabled to allow access to the database from client computers (Some versions of SQL Server disable remote connections by default); the administrator might have to create a Windows Firewall exception to accept remote connections.



## Installation Process of ACS Local Workstation

### Step 1

The ACS Local Workstation installation package can be downloaded via web at <https://acslocalworkstation.outcome.com/app/download.html>. The website will display the system requirements and provide a link for downloading a copy of this guide. Clicking on the “Download Now” button will initiate the download process for the installation package.

#### ACS LOCAL WORKSTATION

Version:	1.0b1
Release Date:	05/07/2010
Download Size:	17.4 MB

[Installation Instructions](#)

#### SYSTEM REQUIREMENTS

- Microsoft® Windows XP, Vista, 7
- 100 MB available hard disk space
- 1 GB RAM
- Microsoft® Internet Explorer 6 or higher, with JavaScript enabled
- Adobe® Flash® Player 9 or higher
- Java Runtime Environment 6 or higher
- Microsoft® SQL Server Database

[Download Now](#)

### Step 2

Download the installation package to your computer (Please note the installation requirements mentioned above prior to installing).

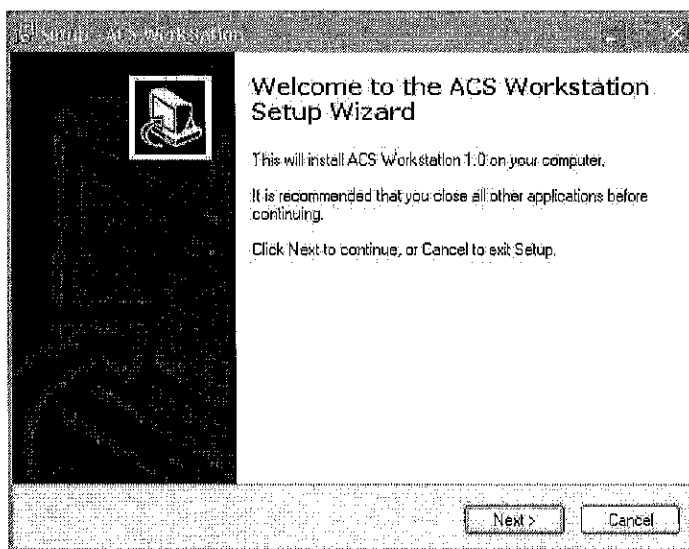




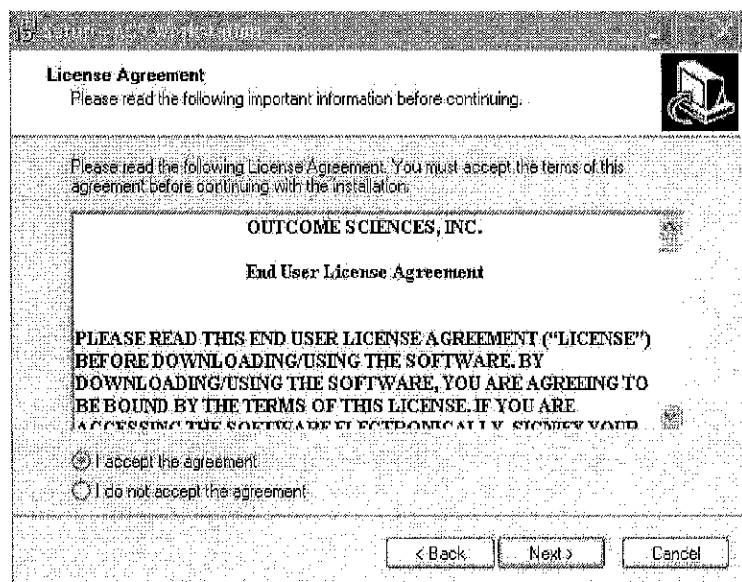
## Step 3

Double clicking the installation package of the ACS Local Workstation application will evoke a “Setup Wizard” window, which requires the user to follow each of the prompts presented to install the application.

Begin the wizard by clicking on “Next.”

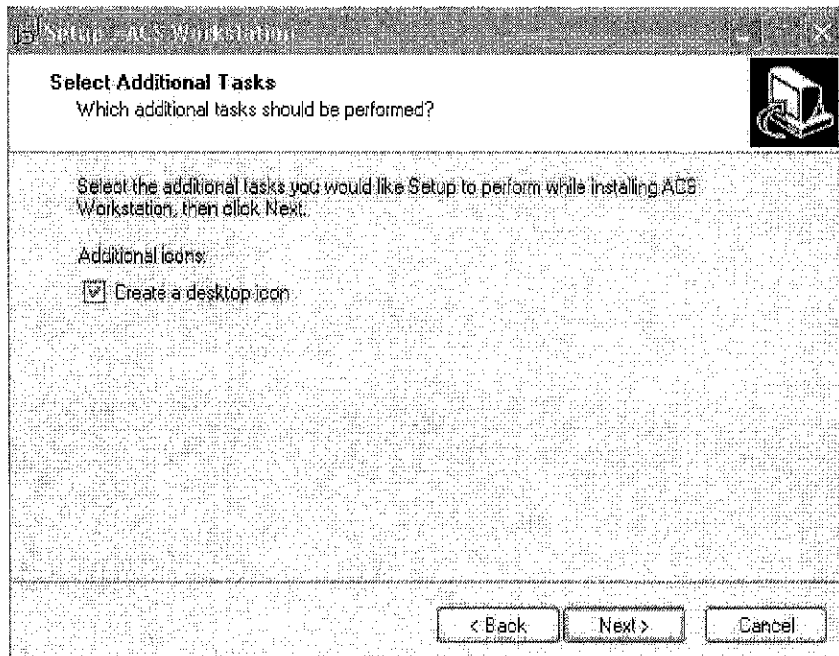


You will be asked to review and accept the End User License Agreement. Select “Accept” and click on “Next” to move to the next screen.

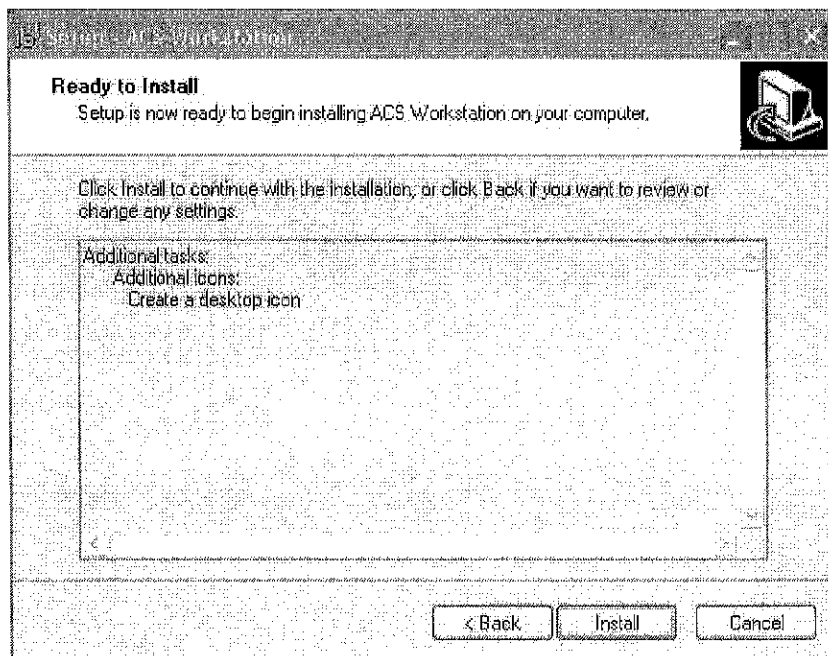




It is recommended that you create a desktop icon for easier access.

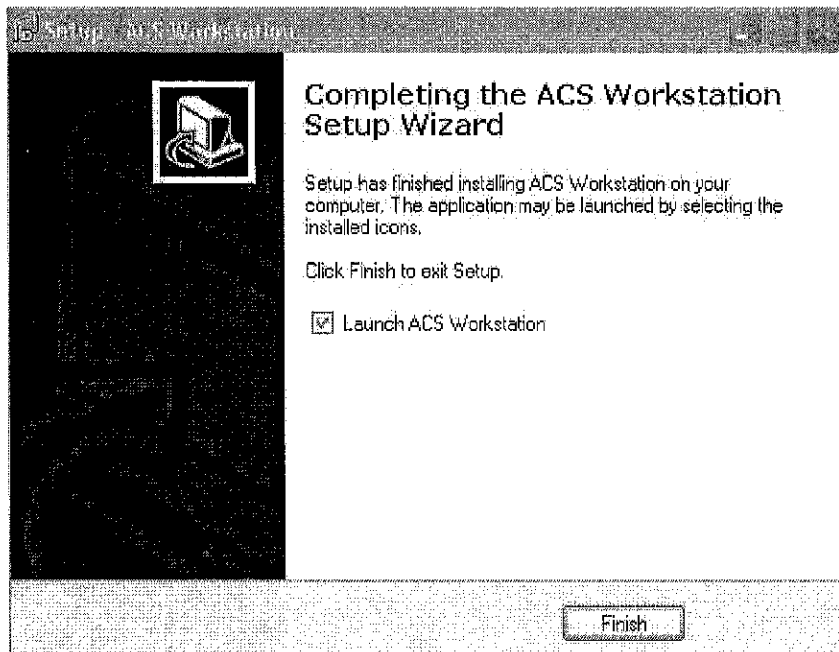


The installation wizard will display a list of components that will be installed. Click on “Install” to finalize the installation.





The installation wizard will inform you that the installation has been completed. Leaving the “Launch ACS Local Workstation” check box marked will launch the application upon clicking on “Finish”.





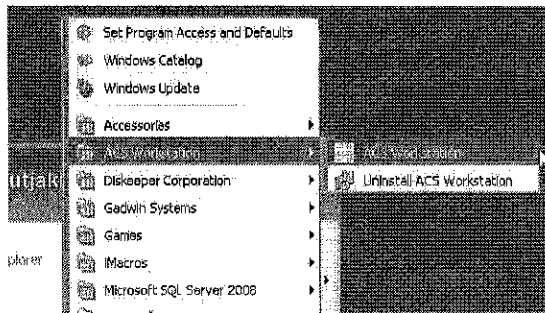


## Application Launch

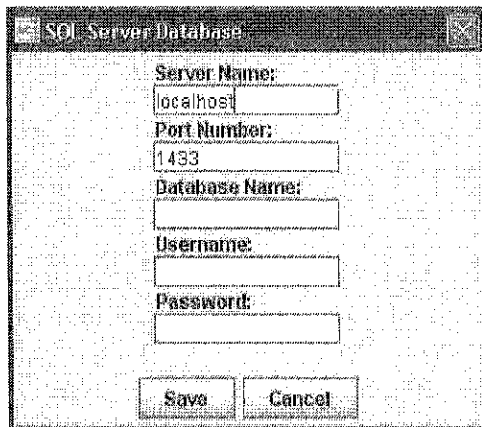
The wizard will create a desktop icon of the ACS Local Workstation.



It will also incorporate the application in the Program Menu.



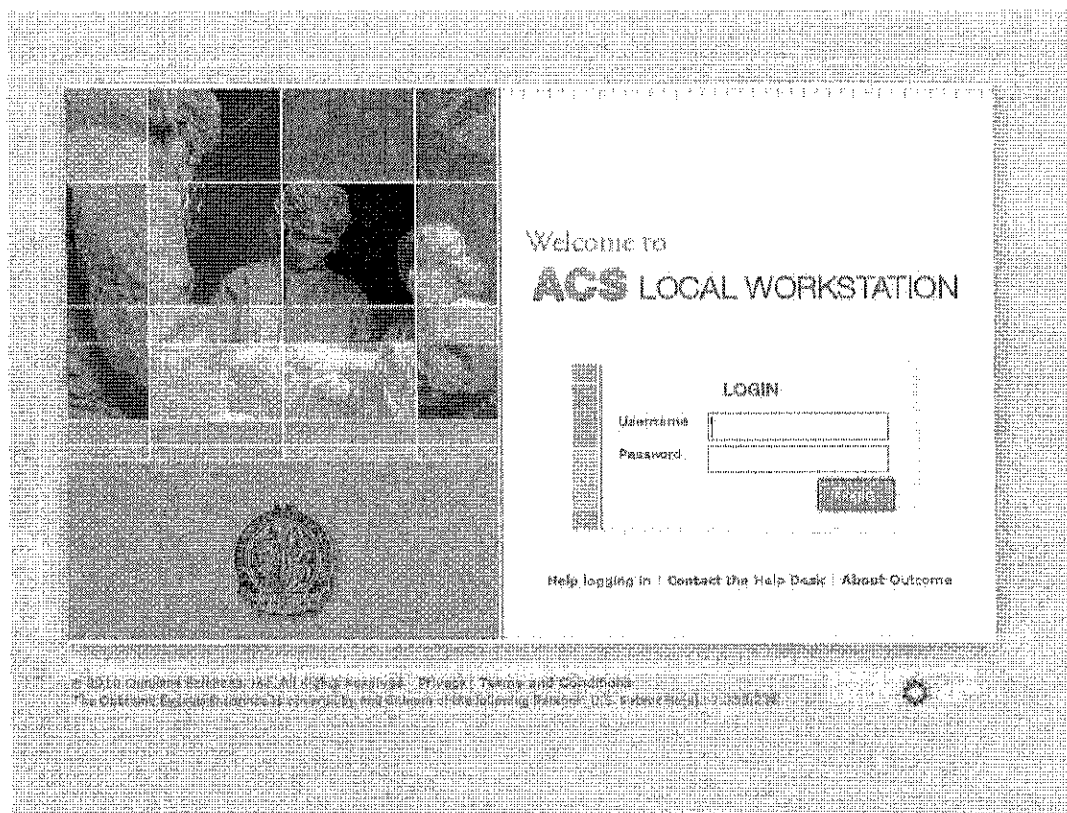
Launching the application for the first time will prompt you to configure your connection to your database and enter your username and password for your local database. Please note this is different from your log in account for entering data in the ACS Local Workstation as described on the next page. Once you enter the applicable information, click on "Save". This information will need to be provided only once during the initial setup of the application unless the administrator wants to change the database login details. If the connection test fails, you will be alerted via a pop-up warning, however, the database configuration screen will remain open for you to correct the parameters. Please refer to the "Troubleshooting" section of this manual for any error messages received during the installation process.



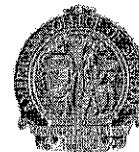


The application will launch a browser and bring you to the main login page for data entry. Entering your username and password will grant you access to the ACS Local Workstation.

Please see screenshot below:

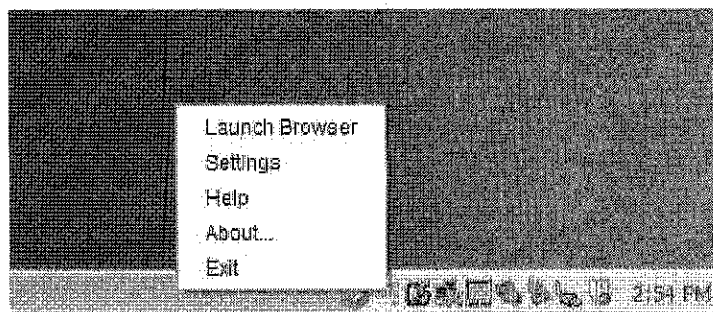


**NOTE:** Please refer to the Troubleshooting section of this manual for any error messages received during the installation process.



## Configuration Options

If the ACS Local Workstation is running on your computer the application icon will place an icon on the system tray. Right clicking on the application icon will display a list of the following options:



- Launch Browser: Allows you to launch a new application window
- Settings: Allows you to configure your database connection settings
- Help: Opens the ACS Local Workstation User Manual
- About: Provides information on the current version of the application
- Exit: Clicking on this option will allow you to exit the application



## Using the Latest Version

When a new version of the desktop application is released, the user will be alerted to the availability of the newer version upon launching the application and entering their username and password. The user will be instructed to download and install the updated version from the project web site.

You must exit the ACS Local Workstation application running on your desktop before proceeding. Follow steps 1-3 as described in the [“Installation Process of ACS Local Workstation”](#) section above.

Please note that you will not need to update or change your database configuration settings. The installation will only replace the current installation. No data will be lost as a result of the update.

A new version of the Local Workstation is available. You must download and install this new version. Please exit the Local Workstation application that is running on your desktop before proceeding.

### ACS LOCAL WORKSTATION

Version:	1.0b1
Release Date:	05/07/2010
Download Size:	17.4 MB

[Installation Instructions](#)

### SYSTEM REQUIREMENTS

- Microsoft® Windows XP, Vista, 7
- 100 MB available hard disk space
- 1 GB RAM
- Microsoft® Internet Explorer 6 or higher, with JavaScript enabled
- Adobe® Flash® Player 9 or higher
- Java Runtime Environment 6 or higher
- Microsoft® SQL Server Database

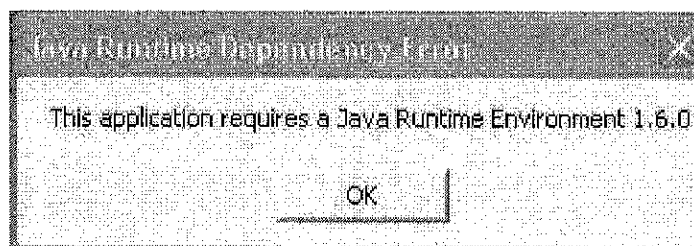
[Download Now](#)



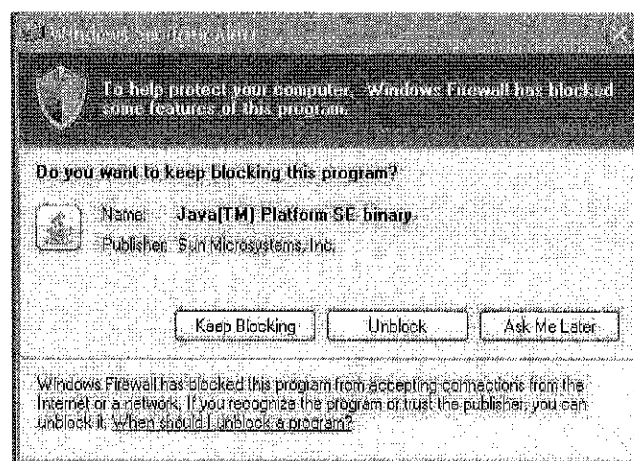
## Troubleshooting

You may encounter the following messages during the installation process of the ACS Local Workstation. Please follow the instructions below for resolving these issues:

**Missing Java Environment message.** The following error will display if Java Runtime Environment 6 or higher is not installed prior to the ACS Local Workstation Installation. Please download the Java environment by clicking the link above and repeat the installation process.



**Blocked Java message.** The following error will display if the firewall settings on your computer block the Java Environment. Please click on “Unblock” to remove this message.



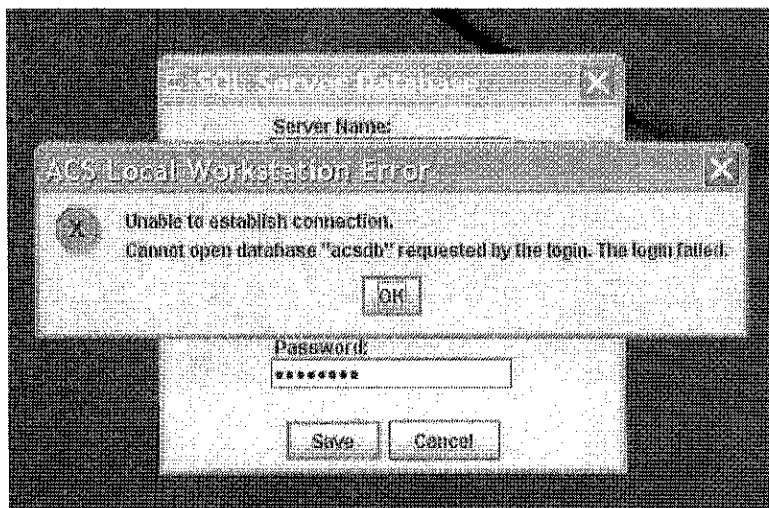


## Connectivity messages:

- 1) The following message will be displayed if the name of the machine where SQL Server is installed was entered incorrectly. Please enter the correct name and click on “Save”.



- 2) The following message will be displayed if the database name was entered incorrectly. Please re-enter the correct database name.

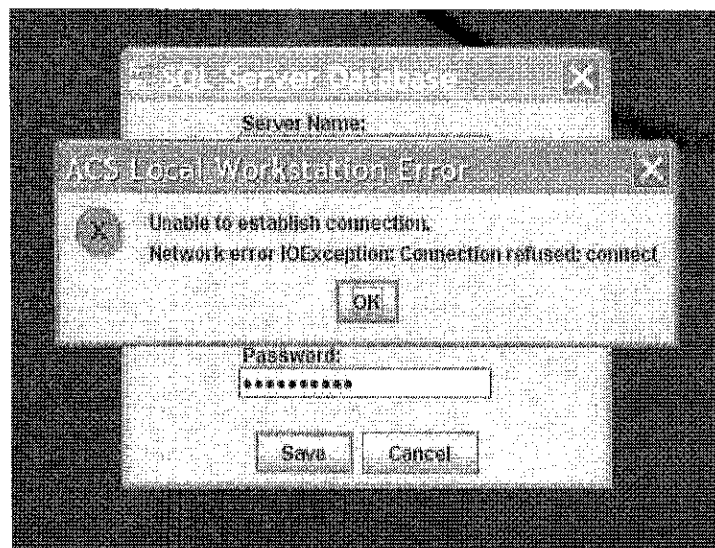




- 3) The following message will be displayed if the database username and password was entered incorrectly. Please re-enter the correct username and password and click on “Save”.



- 4) The following message will be displayed if the port number for the database server was entered incorrectly. Please re-enter the correct port number and click on “Save”.





## Questions/Concerns

Please contact the ACS NSQIP and ACS BSCN Technical Support teams at 1-877-600-7237 or email:

ACS NSQIP: [techsupport@acsnsqip.org](mailto:techsupport@acsnsqip.org)

ACS NSQIP Pediatric: [techsupport@pediatric.acsnsqip.org](mailto:techsupport@pediatric.acsnsqip.org)

ACS BSCN Bariatric: [techsupport@acsbscn.org](mailto:techsupport@acsbscn.org)





## **Transition Related IT FAQs**

Version 1.0

May 10, 2010

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## **1. Security/Compliance for Web-based Workstation**

**1.1. *Please describe the procedures that cover the physical computer security (e.g. room access, fire, flood, etc.)?***

All servers used to host customer/site applications are housed in a commercial co-location facility. These facilities provide access control, fire protection, power conditioning, backup power (UPS and generator), High-speed internet access, cooling and hands-on assistance when needed. Access to these facilities is controlled by access lists, key cards and biometrics.

**1.2. *Are environmental conditions monitored seven days a week, 24 hours per day?***

The data centers are manned and monitored 24x7x365 by employees of the data center provider. This includes access and environmental conditions.

**1.3. *What is Outcome's system back up procedures?***

All databases and application code, configuration files, and artifacts are backed up nightly and transmitted by private network to Outcome's central data facility in Cambridge. Data are backed up to tape and archived by a nationally recognized archival vendor.

**1.4. *Regulatory Compliance***

All of Outcome's solutions are fully privacy compliant and mesh seamlessly with an organization's existing privacy protocols. Outcome has worked closely with the ACS to ensure privacy compliance, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the EU Privacy Directive.

**1.5. *Does the Enhanced Web-based Workstation meet HIPAA requirements?***

The Enhanced Web-based Workstation uses encryption to protect data "in motion" as it travels from point to point over the internet. This encryption is done using secure sockets layer and bit key applications sufficient to render the information travelling over the internet as "unusable, unreadable, or indecipherable to unauthorized individuals" consistent with HIPAA and the HITECH Act. When the data arrives in the ACS NSQIP database and is data "at rest" in Outcome's servers, it is no longer encrypted; however, it is secured and protected by stringent application level controls, network controls and physical access controls. In addition, Outcome utilizes secure, off-site hosting facilities that are monitored 24x7x365, with access controlled by security personnel and/or biometric security systems. Access to PHI by workforce members of ACS and/or Outcome is limited in accordance with HIPAA rules applicable to business associates. This is the same security level for online and workstation data with the exception of the locally stored PHI.

The above steps meet or exceed federal requirements for information security and privacy and are consistent with industry standards for data privacy.

**1.6. Reliability**

Outcome focuses not only on collecting but also on securing data. Outcome offers a secure facility and failover processes to keep your data safe. Outcome maintains system security through both physical and logical methods. Databases are maintained in a secure, access controlled and monitored facility. The mechanisms employed are in-band processes (encryption, authentication, and intrusion detection), out-of-band processes (user identification, secure storage and back-up, data redacting, and non-modifiable audit trails), and system redundancy. Additionally, an external assessment of system security is routinely performed by an independent, expert third party.

**1.7. How is access to the system maintained?**

Access to the Outcome system is based on defined user roles. These roles determine the specific menus, tasks, and information to which a user has access. By integrating this technology with standard procedures for user definition, password selection and updating, and other features, we can prevent unauthorized access to the study and secure information.

Outcome's security standards meet or exceed those established for privacy protected and/or other sensitive HCFA information sent over the Internet.

**1.8. How are the systems access controlled on the server and client workstation including encryption method, capability to view passwords and password integrity?**

Systems are accessed via individual username and password. Passwords are encrypted at the browser using a DES encryption key and transmitted to the server where they are compared to the encrypted password stored in the database. The communication of the encrypted password is secured using SSL. Passwords are never visible in unencrypted format.

**1.9. How is disaster recovery setup (Hot, Warm, Cold or Other)?**

It depends on the point of failure, if the App server or Instance fails the recovery is warm, if the database fails the recovery is hot (clustered oracle).

**2. Enhanced Web-based Workstation and Local Workstation Features and Functionality**

**2.1. What is the new Enhanced Web-based Workstation?**

The Enhanced Web-based Workstation is an online application which can be easily accessed 24/7 from any computer with internet access. Sites will not be required to purchase any servers or take extra security precautions as the entire platform is hosted and maintained by Outcome Sciences

**2.2. *What browsers can be used to access the Enhanced Web-based System?***

The suggested browser is Internet Explorer 7.0 or higher, but the following additional browsers are also supported, Firefox 2 or higher, Safari 3 or higher

**2.3. *What Username and Password will I use to access the system?***

Users will use Usernames and Passwords that they currently use to access ACS NSQIP.

**2.4. *Will the system allow me to change my password?***

Users can change their password and update their contact information at any point in the Enhanced Web-based Workstation

**2.5. *We participate in multiple programs. How will we access each program?***

A separate username and password will be provided to you for each program.

**2.6. *If I log in with an incorrect password will I be locked out of the system?***

After 5 unsuccessful login attempts users will be locked out of the system and will need to contact the ACS NSQIP Tech Support Desk for a new password.

**2.7. *Will the system automatically log me out if I am inactive?***

The system will provide a warning message after 55 minutes of inactivity that the user will be logged out in 5 minutes. After 60 minutes of inactivity the system will automatically log out.

**2.8. *What are the specific password requirements?***

Passwords must be 6 characters in length and must contain at least 1 number and 1 letter.

**2.9. *Will the Enhanced Web-based Workstation allow us to track patient sampling?***

Patient sampling will continue to be tracked externally of the Enhanced Web-based workstation

**2.10. *How will data be entered in the demographics form?***

Data in the demographics form can be entered both manually and via data automation tools

**2.11. *What is the Local Workstation?***

The Local Workstation is software that is installed on a user's local computer. The Local Workstation will require MS SQL Server and IT support to install.

**2.12. Does the Local Workstation require having administrative access for installation?**

Administrative privileges are required for the installation of the local workstation

**2.13. What system requirements are needed to support the Local Workstation?**

- The minimum system requirements are as follows:
- MS Windows (No specific operating system)
- Java Runtime Environment (v6+), downloadable from <http://java.com/download>
- Internet Explorer (v6; (v7+ recommended)) with JavaScript enabled
- Flash Player plugin (v9+), downloadable from <http://www.adobe.com/products/flashplayer/>
- 100 MB of disk space
- 1gb RAM

**2.14. Will anti-virus software affect the local workstation installation process?**

Anti-virus software will not affect the ability to install or use the Workstation. However, the user will need to have privileges to install programs.

**2.15. Is active x required?**

Active X is not required.

**2.16. What type of Database server will my Local Workstation need?**

The local workstation will need to connect to MS SQL Server (Express or Full Edition).

**2.17. What custom fields are available with the Enhanced Web-based Workstation?**

A separate section of the case form allows for each hospital to have access to custom fields. Currently each hospital will be able to utilize 10 custom "text" fields, 10 custom "integer" fields and 5 custom "date" fields to capture hospital specific information.

**2.18. Will the existing CPT codes and ICD-9 codes dictionaries be maintained? Will the codes be updated for any of the programs?**

The CPT and ICD-9 codes look up functionality will be maintained. Data entry of CPT and ICD-9 codes in patient cases will be enhanced by easier navigation and search options of the platform

**2.19. Will we continue to have the "repeat above date" feature as well as "set all fields to 'No' feature as we have now?**

The "Repeat above date" feature will continue to be available for a number of fields. The "set all features to No" feature will be replaced by form control functionality. In many fields an option to select all responses of a section of a case to "Unknown" will be available. Similarly, some fields will default to "No" upon creating a new case. Details of these functionalities will be provided in future trainings and documentation.

**2.20. How will new software release versions be distributed and deployed?**

Enhanced Web-based Workstation: Updates to the Enhanced Web-based Workstation will be applied automatically by the system. Updates are done on Saturday mornings.

Local Workstation: Only updates to local PHI will require an update to the Local Workstations. Local users will be notified when there are updates.

**2.21. Will sites be notified of regularly scheduled updates to the system?**

Users will be notified in advance of any system changes to the functionality of the Enhanced Web-based and Local Workstations.

### **3. Data Automation**

**3.1. Will data automation be available for all programs?**

Data automation will be available for the ACS NSQIP.

**3.2. Will data automation be supported for the Enhanced Web-based workstation and Local Workstation?**

Data automation will be supported for both types of workstations

**3.3. Will there be changes to the data table structure and schema of our database?**

The structure and schema will be changed for the local workstation.

**3.4. Will there be a feature to manually upload files to the platform?**

An XML Uploader will be available for hospitals to upload data to the ACS NSQIP program. Detailed steps on the XML Uploader functionality will be provided to hospitals the week of May 24th 2010 and this will replace the existing QCMitt functionality.

**3.5. Will a web service be available?**

Web Services will not be available for the initial release.



## **4. Data Migration**

### ***4.1. Will we need to modify our existing XML specifications?***

The new XML specifications will be very similar to the current format. Minor modifications might be required to conform to the new specifications. Detailed XML specifications will be provided to hospitals the week of May 24<sup>th</sup> 2010.

## **5. Integration**

### ***5.1. Will the workstations link to Electronic health records?***

At this time, there will be no integration between the Local or Enhanced Web-based Workstation and electronic health records.

## **6. Online Reports**

### ***6.1. Will my hospital be able to run our existing reports?***

All reports that exist in the current system will continue to be available in the new Enhanced Web-based workstation once the migrated data is available. The reports can be run on demand and will provide real-time information. The new platform allows for increased filtering and exporting capabilities. Reports can be printed and exported to Excel and .csv formats. Until the data has fully migrated to the new platform, sites can continue to run reports on the QCMetrix platform.

## **7. Preparatory Steps for Transition**

To help ensure a smooth transition to new Enhanced Web-based workstation or local workstation, some preparatory steps can be started before moving to the new system. The first step in planning for your system upgrade is to determine if you will be using the new Enhanced Web-based workstation or the local workstation. This will become important as we get closer to the transition day, but may require working with the entire site team to make the correct choice.

The transition will take place in several steps and each step will be communicated as the time approaches. The following steps are part of the overall upgrade to the new system. Along with each of these steps is information or actions that are needed to complete the step.

### ***Step 1: Local Data Migration Test Phase***

**Description:** During this phase a local migration utility will be distributed to test the process of extracting your local PHI information from the existing system

**Information Required:** In order to run this utility you will need to know the current location and connection information for the existing PHI data store. Specifically, you need to know the ODBC connection string, username and password.

**Actions:** The migration utility (more information on availability will be forthcoming) will be run to validate the structure and ability to connect to your existing database.

***Step 2: Workstation Installation (local workstation sites only)***

**Description:** During this phase the local workstation installation will be performed. Note this is only for the local workstation sites, not the new Enhanced Web-based workstation sites.

**Information Required:** The local workstation installation requires connection parameters to the new database for PHI (see actions). Specifically, you need to know the ODBC connection string, username and password.

**Actions:** The local workstation requires a MS SQL Server Express or higher database.

***Step 3: XML Uploader installation (QCMitt replacement) and Local Data Migration***

**Description:** During this phase the new uploader utility will be installed and the local migration utility will be run to migrate your local PHI Data.

**Information Required:** You will need to know your username and password to the new system. Also, if your site installed the local workstation you will need to have the connection information to the new PHI database.

**Actions:** During this phase you will log into the system to validate your username and password, install the new uploader, run the migration utility resulting in PHI uploader files and use the new uploader to migrate the local PHI information.

## **8. General Program and Transition Questions**

### ***8.1. Who should I contact for support?***

For general program support related to the transition, please contact Amy Hart at 312-202-5213 or email: [ahart@facs.org](mailto:ahart@facs.org).

For technical support related to the transition, please send emails to [techsupport@nsqip.org](mailto:techsupport@nsqip.org).

### ***8.2. Where can I find updated information about the transition online?***

The recent webinars can be found on the secure portion of the ACS NSQIP website at [acsnsqip.org](http://acsnsqip.org). For SCRs, the information is posted on the "SCR Toolkit" portion of the website. For Surgeon Champions, the materials are posted on the "Reports" page.

**8.3. How can I view the recorded webinars?**

Recording of the webinars are posted with the transition information on the secure portion of the website (See above).

**8.4. Are there any changes made to the existing cycle structure?**

There are no changes to the existing cycle structure.

**8.5. Are there any changes in the timeframes for data entry?**

Time frames, with the exception of some differences during the transition period will remain the same. Data entry timeframes during the transition period will be fully explained in the "Getting Started" Toolkit and during SCR data collection training webinars to be held the week of May 24<sup>th</sup>.

**8.6. Some existing functionalities were not displayed on the webinars. Will those be available?**

The recent webinars featured only a brief overview of the new Enhanced Web-based workstation. Complete functionality will be available for the launch day of June 1st 2010. Training will be available for Web-based users June 1<sup>st</sup> and June 2<sup>nd</sup>. Training for Local users will be June 7<sup>th</sup> and June 8<sup>th</sup>.

**8.7. What training do you provide for the ongoing support of the system?**

Trainings will be available through self guided online modules and scheduled webinar sessions.

**8.8. Can we use both the Enhanced Web-based Workstation and the local version concurrently?**

Local Workstation Users can log into the Web-based Workstation to run reports. Local PHI will not be available from the Web-based Workstation for local workstation users, but Local users will be able to see all other data as read only. Local users will not be able to update data through the Web-based Workstation. Web-based users will not have access to the Local Workstation.

**8.9. I am participating in a pilot program, are there additional steps that I need to take?**

No additional steps are needed at this time.

**8.10. What will happen to my existing data?**

Users will migrate local PHI to the Web-based and Local Workstations at the "go live" date. All other existing data for Web-based Users will be available from the Outcome system on July 16<sup>th</sup>. For local users existing data will be available August 14<sup>th</sup>. A detailed overview of the data migration schedule will be included in the "Getting Started" Toolkit.

**8.11. *Have changes been made to the existing forms and data fields that are currently captured?***

Minor changes have been made to the existing forms and data fields that are currently collected. Information regarding the changes will be included in the "Getting Started" Toolkit and will also be covered during the SCR data collection training webinars to be held the week of May 24<sup>th</sup>.

**8.12. *If I choose the Local Workstation can I move to Enhanced Web-based Workstation at a later date?***

It will be possible to move to the Enhanced Web-based Workstation after go live. Sites will need to contact ACS to change their settings to a Web-based Site and then they will need to migrate their Local PHI into the Enhanced Web-based Workstation.