Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture Database CONFIDENTIALITY AGREEMENT FOR DATA REQUESTERS FOR RESEARCH PURPOSES

- 1. This Confidentiality Agreement (CA) specifies the terms and conditions for release and use of electronic or hardcopy data ("Data") from the Agency for Healthcare Research and Quality (AHRQ) Surveys on Patient Safety Culture[®] (SOPS[®]) Hospital Survey Version 1.0 and/or Version 2.0 ("SOPS Hospital Survey") Database ("Database"). Any individual ("Data Requester") seeking to obtain or use Data from the Database must sign and submit this CA to AHRQ's contractor, Westat, before release of the Data may be granted. This CA shall not be modified or altered in any manner except with the express permission of the AHRQ contractor administering the Database.
- 2. The Database is funded by AHRQ and managed and administered by Westat, a private research organization under contract with AHRQ. The purpose of the Database is to establish a central repository of SOPS Hospital Survey data to facilitate comparisons across health care organizations. The Database is populated with SOPS Hospital Survey data through the voluntary participation of organizations ("Participating Organizations") that have implemented the SOPS Hospital Survey and have been willing to submit their SOPS Hospital Survey data to Westat for inclusion in the Database.
- 3. Participating Organizations have provided their SOPS Hospital Survey data to the Database for analysis and aggregate reporting under the terms of the Survey on Patient Safety Culture Database Data Use Agreement. Data Requesters may obtain access to hospital-identifiable SOPS Data only with the approval of AHRQ and Westat and the written authorization of each Participating Organization. Participating Organizations may provide for blanket, pre-approval for release of their Hospital-Identifiable SOPS Data to all Data Requesters whose proposals have been reviewed and approved by AHRQ and Westat. If a hospital does not authorize a blanket, pre-approval for release of their Hospital-Identifiable SOPS Data, and does not prohibit the release of such Data, then requests for hospital-identifiable Data are subject to a review process where each Participating Organization is asked to provide written authorization for release of its hospital-identifiable Data to specific Data Requesters on a case-by-case basis.
- 4. Use of hospital-identifiable SOPS Data (with written authorization from Participating **Organizations).** This CA implements the data protections of the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute. The AHRQ confidentiality statute, Section 944(c) of the Public Health Service Act (42 U.S.C. 299c-3(c)), requires that data collected by AHRQ or one of its contractors (including Westat) that identify establishments be used only for the purpose for which they were supplied. For the purposes of this CA, a Participating Organization is considered an "establishment" under 42 U.S.C. § 299c-3(c). Per CA item 3, if a Participating Organization grants express written authorization to release its hospital-identifiable Data, then such hospital-identifiable Data may be provided to the Data Requester only for the purposes the Data Requester provides in Data Requester's Research Proposal. Valid purposes for using hospital-identifiable Data do not include the use of Data concerning Participating Organizations for public reporting, commercial or competitive purposes involving those Participating Organizations, or to determine the rights, benefits, or privileges of Participating Organizations. Misuse or unauthorized use of hospital-identifiable Data may be deemed to violate the AHRQ confidentiality statute and may trigger its penalty provisions. Violations of the AHRQ confidentiality statute are subject to civil monetary penalties under 42 U.S.C § 299c-3(d).

- 5. By signing this CA, the undersigned Data Requester agrees to abide by the following specific terms with respect to all SOPS Hospital Survey Data sets:
 - a. I will not use, and will prohibit others from using or disclosing, the Data set(s) (or any part) except for the purposes specified in the Research Proposal.
 - b. I will ensure that the Data are kept in a secured environment and that only authorized users will have access to the Data.
 - c. I shall limit the use or receipt of the Data set(s) to the individuals who require access in order to perform activities permitted by this CA for the purposes specified in the Research Proposal. I will require others employed in my organization, and any agents or contractors of my organization, as well as any individuals outside of my organization, who will use or have access to the Data set(s), to sign a copy of this CA specifically acknowledging their agreement to abide by its terms, and I will submit those signed CAs to AHRQ's contractor, Westat, before granting them access to the Data.
 - d. I will not release or disclose, and will prohibit others from releasing or disclosing, the Data set(s) (or any part) to any person who is not a member, agent, or contractor of my organization, except with the approval of AHRQ directly or through its contractor, Westat.
 - e. I will not release or disclose, and will prohibit others from releasing or disclosing, any Data that identifies persons or Participating Organizations directly or indirectly, except as permitted under this CA and in accordance with the above-mentioned AHRQ confidentiality statute.
 - f. I will not release, disclose or make public any identifying information about Participating Organizations at any time in any analyses or summaries of results using hospital-identifiable Data.
 - g. I will not attempt to use, and will prohibit others from using, the Data set(s) to learn the identity of any person included in the Data set(s) or to contact any such person for any purpose.
 - h. I will not attempt to contact and will prohibit others from contacting Participating Organizations for the purpose of verifying information supplied in the Data set. Any questions about the Data must be referred exclusively to AHRQ or AHRQ's contractor, Westat.
 - i. In accordance with the AHRQ confidentiality statute, I will not use and will prohibit others from using the Data set(s) concerning individual Participating Organizations (1) for commercial or competitive purposes involving those Participating Organizations; (2) to determine the rights, benefits, or privileges of individual Participating Organizations; or (3) to report, through any medium, data that could identify, directly or by inference, individual Participating Organizations.
 - j. Upon notification that AHRQ is suspending or terminating this CA, I will comply with any instructions AHRQ or its contractor provides under this CA, including but not limited to instructions regarding my access to or custody of Data that is subject to this CA.
 - k. I will indemnify, defend, and hold harmless AHRQ, its contractor Westat, and the Participating Organizations that provide Data to the SOPS Hospital Database from any or all claims and losses accruing to any person, organization, or other legal entity as a result of violation of this CA. This provision applies only to the extent permitted by Federal and State law.

I. If I receive hospital-identifiable SOPS data, I will include the following acknowledgment in any publication or presentation using hospital-identifiable SOPS data:

"The Surveys on Patient Safety Culture[®] (SOPS[®]) Hospital Survey data used in this analysis were provided by the SOPS Hospital Database. The SOPS Hospital Database is funded by the U.S. Agency for Healthcare Research and Quality (AHRQ) and administered by Westat under Contract No. GS-00F-009DA/75Q80123F80005."

I will send copies of all publications using hospital-identifiable SOPS data to Westat.

- 6. **Safeguards.** In addition to abiding by the express terms of this CA, the Data Requester agrees to exercise reasonable caution and use appropriate safeguards to prevent the unauthorized use or disclosure of the Data set(s) other than as permitted by this CA.
- 7. **Reporting violations of this CA.** The Data Requester agrees to report any violations to AHRQ or its contractor Westat, immediately upon becoming aware of any violation of this CA, but no later than twenty-four (24) hours after becoming aware of any violation of this CA. AHRQ or Westat will report any violations of this CA to participating hospitals.
- 8. **Term, breach, suspension and termination of this CA.** This CA shall continue in full force and effect unless and until terminated by AHRQ or its contractor. Any breach of the terms of this CA, as determined by AHRQ and its contractor in their sole and absolute discretion, will be grounds for immediate suspension or termination of this CA. The Data Requester understands and acknowledges that suspension or termination of this CA does not abrogate the terms of this CA as they may apply to the Data Requester.
- 9. Reporting to the United States Department of Health and Human Services. If the Data Requester fails to remedy any breach or violation of this CA to the satisfaction of AHRQ, and if termination of the CA is not feasible, AHRQ may report Data Requester's breach or violation to the Director of AHRQ, and the Data Requester agrees that he or she shall not have or make any claims against AHRQ or Westat with respect to such report(s).
- 10. **Other Remedies.** If the Data Requester fails to remedy any breach of this CA to the satisfaction of AHRQ, AHRQ may take any action authorized by law to remedy such breach or prevent its recurrence.

I understand that this CA is required by the United States Agency for Healthcare Research and Quality to ensure responsibility for compliance with applicable statutory confidentiality requirements.

My signature indicates my agreement to comply with the above-stated requirements with the knowledge that any violation of the AHRQ confidentiality statute is subject to a civil penalty of up to \$10,000 under 42 U.S.C. § 299c-3(d), and that deliberately making a false statement about this or any matter within the jurisdiction of any department or agency of the Federal Government violates 18 U.S.C. § 1001 and is punishable by a fine of up to \$10,000 or up to five years in prison.

(Name - Type or Print)	(Job Title)
(Project Title)	
(Project Timeline)	
(Organization)	
(Address 1)	
(Address 2)	
(City)	
(State)	(ZIP Code)
(Phone)	
(Email)	
(Signature)	(Date)

The information above is maintained by AHRQ only for the purpose of enforcement of this CA.

Completed Confidentiality Agreements should be signed and emailed to

SOPSResearchData@westat.com SOPS Research Databases Westat Phone: 1-855-959-2740 Email: <u>SOPSResearchData@westat.com</u>

Submit additional signed CAs for other employees in your organization, contractors of your organization, as well as any individuals outside of your organization, who will use or have access to the Data set(s).