

Attachment A-6: Hospital SOPS Data Use Agreement (DUA)

Survey on Patient Safety Culture Database Data Use Agreement

Instructions

1. Westat has pre-signed this Data Use Agreement (DUA) in its current form. Any changes or modifications to the DUA other than those required to complete the DUA, such as contact information, will require review and execution, by both parties, of a new DUA or addendum.
2. Data collection vendors may not sign and submit this DUA on behalf of a health system or hospital (even if they have been given permission by the health system or hospital to handle the actual submission of data). Only a duly appointed representative from a health system or hospital may sign this DUA.
3. Please sign and return this DUA by mail, scanning and emailing, or faxing a signed copy to:

Steve Wilson
Westat
RA 1107
1600 Research Boulevard
Rockville, MD 20850

Fax: 1-888-852-8277 (toll free)

Phone: 1-888-324-9790 (toll free)

Email: DatabasesOnSafetyCulture@westat.com

Survey on Patient Safety Culture Database Data Use Agreement

1. This Data Use Agreement (DUA) is made by and between Westat and the organization named below (hereinafter termed “Participating Organization”) as well as any hospitals listed under item 14 on page 3 of this Data Use Agreement (collectively the “Parties”).

VERY IMPORTANT: Type or write in the name of the Participating Organization above. If more than one hospital is represented, list the name of the entire health system above, and under item 14 on page 3 of this Data Use Agreement, LIST THE NAME OF EACH INDIVIDUAL HOSPITAL for which data will be submitted.

2. This DUA specifies the terms and conditions of Participating Organization’s submission of its Survey on Patient Safety Culture (SOPS) data to Westat for participation in the SOPS Database (hereinafter termed the “Database”).
3. The purpose of the Database is to establish a central repository of SOPS survey data to facilitate comparisons across health care organizations. The Database will be populated with SOPS survey data through the voluntary participation of organizations that have implemented the SOPS survey and are willing to submit their SOPS survey data to Westat for inclusion in the Database.

The Database is funded by the Agency for Healthcare Research and Quality (AHRQ) and managed and administered by Westat, a private research organization under contract with AHRQ. Westat will operate the Database to comply with the provisions in this DUA. Within this framework, Westat will manage and administer the Database in its discretion, but will seek and be guided by the advice and counsel of the SOPS Database Technical Expert Panel (TEP) established by Westat in accordance with its contract with AHRQ to provide input throughout the design, development and administration of the Database. The TEP consists of 15 representatives knowledgeable about hospital patient safety and quality from hospital stakeholder organizations and selected health care systems as well as government agencies concerned with hospital health care.

4. Participating Organizations will provide their survey data to the Database for analysis and reporting according to the terms specified in this DUA. By agreeing to participate in the Database, each Participating Organization agrees to make a good faith effort to provide data, as specified by the data specifications outlined for the SOPS Database for inclusion in the Database (collectively referred to as the “Data”), including:
 - 4.1 A copy of the final SOPS survey instrument(s) administered, including copies of paper and/or web-based versions as applicable, showing all survey instructions and items administered. If more than one version of the SOPS survey was administered, a copy of the final SOPS survey instrument must be provided with the corresponding results for each version for which data will be submitted to the Database;
 - 4.2 Participating Organization’s final, respondent-level SOPS survey data, as collected by Participating Organization itself or by a survey data collection vendor, according to the data specifications outlined for the Database; and
 - 4.3 Selected organizational characteristics data (e.g., facility type, bed size, teaching status, etc.) and background information related to survey administration (e.g., mode and dates of administration, sample size, response rate, etc.).
5. Funding for the routine operation of the Database is provided by AHRQ.
6. Participating Organization’s Data will be accepted into the Database provided that the version of the SOPS survey administered by Participating Organization is deemed acceptable by Westat (i.e., not modified substantially from the original SOPS instructions and items) and the Data submitted by Participating Organization are deemed acceptable. Westat will promptly notify Participating Organization of any problem with the survey version(s) administered or with the Data submitted. If the survey version administered is acceptable but the Data submitted are problematic, Westat will make a good faith effort to work with Participating Organization to complete or correct the Data submission, but reserves the right to not include incompatible or flawed Data in the Database.

7. Participating Organization's data files will be aggregated for comparative purposes along with other Participating Organizations' Data in the Database. Only Westat and duly authorized representatives appointed by AHRQ will have access to the source Data provided by Participating Organization.
8. Westat will produce a standard SOPS Database Comparative Report providing aggregate statistics on SOPS survey composite scores and items across all Participating Organizations and across various subsets of Participating Organizations (e.g., by facility type, bed size, etc.). Only aggregate data will be reported, and only when there are sufficient data so that such aggregation will not permit the identification of Participating Organizations by other Participating Organizations or the public. The Database Report will be made available in the public domain and to Participating Organizations through electronic media at no charge. The Report will not identify individual Participating Organizations by name.
9. Westat may conduct psychometric analyses of the aggregate data to examine its distributional properties (variability, missing data, skewness), and to assess the factor structure and reliability of the safety culture dimensions. In any data analysis reports that may be produced, such reports will not identify individual Participating Organizations by name and results will only be reported in a manner that will not permit the identification of Participating Organizations.
10. In accordance with the AHRQ confidentiality statute [at 42 USC 299c-3(c)], Westat agrees to establish appropriate and necessary administrative, technical, and physical procedures and safeguards including limiting access and appropriate staff training to protect the confidentiality of the Data and to prevent the unauthorized use or access to it.
11. 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 purposes for which the data were supplied. Westat may grant access to Participating Organization's data files according to the following provisions:
 - 11.1 **Release of De-Identified Hospital SOPS Data:** Access to data files that do not identify individuals or individual Participating Organizations or their associated hospitals and do not permit re-identification may be granted by AHRQ and Westat without the specific authorization of Participating Organizations whose data are included as part of the aggregate data files. These data files may include variables describing the Participating Organization according to types (e.g., teaching status, hospital bed size categorization, profit status, region, etc.).
 - 11.2 **Release of Hospital-Identifiable SOPS Data for Research Purposes:** AHRQ and Westat periodically receive requests from researchers interested in linking Hospital SOPS data to other measures, such as patient safety and quality outcome data. These studies require hospital-identifiable data, or data that can be linked to a specific hospital through the use of hospital identifiers such as hospital name, hospital address, AHA ID or Medicare Provider ID.

Valid purposes for using hospital-identifiable SOPS data **include** research linking such data to outside datasets. Valid purposes **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.

Individuals requesting hospital-identifiable SOPS data (hereinafter termed "Data Requesters") sign a Confidentiality Agreement in which they agree with the following requirements. Data Requesters agree that they: 1) will not release or disclose any hospital-identifiable SOPS data that identifies persons or Participating Organizations directly or indirectly and will not release, disclose or make public any identifying information about Participating Organizations at any time in any analyses or summaries of results; 2) will not attempt to learn the identity of any person included in the hospital-identifiable SOPS data or to contact any such person for any purpose and will not attempt to contact Participating Organizations for the purpose of verifying information supplied in the hospital-identifiable SOPS data set; 3) will not use, and will prohibit others from using or disclosing, the hospital-identifiable SOPS data except for the purposes specified in their Research Proposal; 4) will ensure that the hospital-identifiable SOPS data are kept in a secured environment and that only authorized users will have access to it; and 5) will limit the use of the hospital-identifiable SOPS data to the individuals who require access in order to perform activities for the purposes specified in the Research Proposal.

- 11.2.1 To allow for the release of hospital-identifiable SOPS data for valid research purposes as specified in 11.2, AHRQ and Westat have developed three options for Participating Organizations to indicate their preferences for providing authorization to release such data. Participating Organizations must select from one of the options below and provide signature in item 15:

Option 1: Selective release of hospital-identifiable SOPS data to specific Data Requesters provided by written authorization on a case-by-case basis. If Option 1 is selected (this is the default if no option is selected in item 15), brief research proposals will periodically be provided to Participating Organizations for review, asking for written authorization to release their hospital-identifiable SOPS data to specific Data Requesters. Research proposals will have been reviewed and approved by Westat and AHRQ before being forwarded to Participating Organizations for review.

Option 2: Pre-approval for release of hospital-identifiable SOPS data to all Data Requesters whose proposals have been reviewed and approved by AHRQ and Westat. If Option 2 is selected, Participating Organizations will grant authority to AHRQ and Westat to review and evaluate all research proposals and authorize release of their hospital-identifiable SOPS data to Data Requesters whose proposals have been deemed acceptable and approved by AHRQ and Westat. By selecting Option 2, Participating Organizations entrust the release of their hospital-identifiable SOPS data to Data Requesters approved by AHRQ and Westat per the valid research purposes specified in 11.2.

Option 3: Prohibiting release of all hospital-identifiable SOPS data. If Option 3 is selected, AHRQ and Westat will **not** release Participating Organization's hospital-identifiable SOPS data to anyone, including researchers. Participating Organization indicates it does **not** want to be offered research proposals to review and will **not** release its hospital-identifiable SOPS data.

- 11.2.2 At any time, Participating Organizations may request from Westat a list of approved Data Requesters who have received Participating Organization's hospital-identifiable SOPS data and obtain a copy of the research proposals which state their intended uses of the data.

12. Westat agrees to use the Data submitted by Participating Organization only for the purposes stated in this DUA.
13. Westat has signed this DUA in its current form. Any changes or modifications to the DUA other than those required to complete the DUA, such as contact information, will require review and execution, by both parties, of a new DUA or addendum.
14. **If Participating Organization represents more than one hospital, use the space below to TYPE OR WRITE THE NAME OF EACH INDIVIDUAL HOSPITAL AND ITS LOCATION (CITY AND STATE) which is represented by Participating Organization and therefore covered under this Data Use Agreement. Attach additional sheet if necessary.**

Add hospitals as needed here



NAME OF HOSPITAL REPRESENTED

LOCATION (CITY & STATE)

PLEASE SIGN, COMPLETE THE INFORMATION BELOW, AND RETURN ALL PAGES OF THIS DATA USE AGREEMENT BACK TO WESTAT.

15. DUA signature and options for release of hospital-identifiable SOPS Data for research purposes (described in item 11.2.1). **SELECT ONE OPTION AND SIGN BELOW.** If no option is selected, Option 1 becomes the default.

- Select one option** →
- Option 1(Default option): Selective release of hospital-identifiable SOPS data to specific Data Requesters provided through written authorization on a case-by-case basis.
 - Option 2: Pre-approval for release of hospital-identifiable SOPS data to all Data Requesters whose proposals have been reviewed and approved by AHRQ and Westat.
 - Option 3: Prohibiting release of all hospital-identifiable SOPS data.

By selecting one of the options above, the duly authorized representative consents to the conditions of release of Participating Organization’s hospital-identifiable SOPS Data under the conditions specified in item 11.2 relevant to the option selected. If no option is selected, Option 1 becomes the default selection.

The undersigned individual hereby attests that he/she is duly authorized to represent the Participating Organization and all hospitals listed under item 14, and in so doing, enters into this Data Use Agreement on behalf of the Participating Organization and the hospitals listed under item 14 and agrees to all the terms specified herein.

Complete Name, Title, and Sign here →

Name: _____
Title: _____

(Signature) (Date)

Participating Organization may change or revoke this consent by sending written notification to Steve Wilson, Westat, RA 1107, 1600 Research Boulevard, Rockville, MD 20850. The request for revocation will not apply to Data already authorized and released prior to receipt of your written request to revoke consent.

16. NAME AND ADDRESS OF PARTICIPATING ORGANIZATION CONTACT

Name and address of person from Participating Organization who is the point of contact for this completed DUA.

Complete as needed →

Name of contact (if different from above): _____
Title (if different from above): _____
Address: _____

Phone: _____ Fax : _____ Email: _____

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The undersigned individual hereby attests that he/she is duly authorized to represent Westat, and, in so doing, enters into this Data Use Agreement on behalf of Westat and agrees to all the terms specified herein.

W. Sherman Edwards
Vice-President, Associate Director at Westat
Surveys on Patient Safety Culture Project

W. Steven Eckert