Instructions

1. All organizations that want to participate in the Hospital Survey on Patient Safety Culture Database must submit a signed Data Use Agreement (DUA) and provide the organization name (hereinafter termed "Participating Organization") and the Participating Organization's point of contact.

Data collection vendors <u>may not</u> sign and submit this DUA on behalf of a hospital or health system (even if they have been given permission by the hospital or health system to handle the actual submission of data). Only a duly appointed representative from a health system or hospital may sign this DUA.

- 2. AHRQ's Contractor, 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.
- 3. Please sign and return a scanned copy of your DUA via:
 - a. Email DatabasesOnSafetyCulture@westat.com,
 - b. Fax 1-888-852-8277,
 - c. Upload to https://sopsdatabase.ahrq.gov/DB/, or
 - d. Mail

AHRQ Surveys on Patient Safety Culture User Network Westat 1600 Research Boulevard Rockville, MD 20850

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

4. Please retain a copy of the fully signed and executed DUA for your records.

If you have any questions or require any additional information, please contact the SOPS Database at 888-852-8277 or by email to DatabasesOnSafetyCulture@westat.com.

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This Data Use Agreement (DUA) is made by and between the Agency for Healthcare Research and Quality (AHRQ), AHRQ's Contractor, Westat, and the organization named below (hereinafter termed "Participating Organization") which includes any hospitals listed under item 13 on page 4 of this Data Use Agreement.

Name of Participating Organization (Hospital or Corporate Office/Health System if more than one hospital is included in this DUA)

Street Address of Participating Organization (Hospital or Corporate Office/Health System)

City State Zip Code

<u>VERY IMPORTANT</u>: Type or write in the name of the Participating Organization above. If more than one hospital location is represented, list the name of the corporate office or overall health system above, and under item 13 on page 4 of this Data Use Agreement, IDENTIFY EACH INDIVIDUAL HOSPITAL LOCATION for which data will be submitted.

- 2. AHRQ's Surveys on Patient Safety CultureTM (SOPSTM) Database is a central repository of SOPS survey data hospitals, nursing homes, medical offices, and pharmacies as measured by a <u>select set</u> of SOPS surveys. This DUA specifies the terms and conditions of Participating Organization's submission of its Hospital Survey on Patient Safety Culture (Hospital SOPS) data for participation in the Hospital SOPS Database (hereinafter termed the "Database").
- 3. The Database is populated with Hospital SOPS survey data through the voluntary participation of organizations that have administered the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) and are willing to submit their Hospital SOPS survey data to AHRQ for inclusion in the Database. Because participating organizations (e.g., hospital, health system) voluntarily submit data to the SOPS Database, the Data do not constitute a nationally representative sample.
 - The Database is funded by the Agency for Healthcare Research and Quality (AHRQ) and managed and administered by AHRQ's Contractor, Westat (hereinafter termed the "Contractor"). AHRQ's Contractor will operate the Database to comply with the provisions in this DUA.
- 4. Participating Organizations will provide their Hospital SOPS survey data to the Database for AHRQ's research, analysis and reporting programs according to the terms specified in this DUA. By agreeing to participate in the Database, each Participating Organization agrees to make every good faith effort to provide data for inclusion in the Database, as specified by the data specifications outlined below. The data provided for inclusion in the Database is collectively referred to as the "Data". Participating Organization's Data include:
 - a) A copy of the final Hospital SOPS survey instrument(s) administered, including copies of paper and/or web-based versions as applicable, for each surveyed population for which data will be submitted to the Database showing all survey instructions and items administered. If more than one version of the Hospital SOPS survey was administered, a copy of each Hospital SOPS survey instrument administered must be provided with the corresponding results for <u>each</u> version of the survey instrument for which data is submitted;
 - b) Respondent-level Hospital SOPS survey data that are de-identified to prevent identification of any individual in the database. Participating Organization submits its final, de-identified respondent-level Hospital SOPS survey data, as collected by the Participating Organization itself or by a survey data collection vendor, according to the data specifications outlined for the Database; and

Public reporting burden for this collection of information is estimated to average 3 minutes per response, the estimated time required to complete the form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-0162) AHRQ, 5600 Fishers Lane, Rockville, MD 20857.

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- c) Selected organizational characteristics data (e.g., ownership, bed size, teaching status, mode of survey administration, dates of administration, sample size, response rate, etc.).
- 5. AHRQ's Contractor agrees to establish appropriate and necessary administrative, technical, and physical procedures and safeguards including limiting access to the Data and providing appropriate staff training to protect the confidentiality of the Data and to prevent the unauthorized use of it or access to it. Only AHRQ's Contractor and duly authorized representatives appointed by AHRQ will have access to the identifiable source Data provided by Participating Organization.
- 6. Participating Organization's Data will be accepted into the Database provided that the version of the Hospital SOPS survey administered is deemed acceptable by AHRQ's Contractor (i.e., not modified from the original Hospital SOPS survey instructions and items) and the Data submitted by Participating Organization are deemed acceptable. AHRQ's Contractor will promptly notify the 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, AHRQ's Contractor will make a good faith effort to work with the 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 used for AHRQ's research, analysis and reporting programs, and the Data will be aggregated along with other Participating Organizations' Data in the Database. AHRQ will report aggregated statistics on Hospital SOPS survey composite scores and items that include all Participating Organizations and present statistics by various organizational characteristics (e.g., ownership, bed size, teaching status, etc.) in a User Database Report posted on the AHRQ website. Results will not publicly identify individual Participating Organizations by name. Only aggregated 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. Results will be made available publicly at no charge.
- 8. AHRQ's Contractor conducts analyses of the Data to examine its distributional properties (variability, missing data, skewness), and to assess the factor structure and reliability of the items and composites, and examine relationships of the Data with organizational characteristics. 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.
- 9. AHRQ and its Contractor, Westat, agree to use the Data submitted by Participating Organization only for the purposes stated in this DUA.
- 10. **Researcher Access to Participating Organization's Data.** 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. AHRQ may grant researchers access to Participating Organizations' Data according to the following provisions:
 - 10.1 Release of De-Identified Hospital SOPS Data: Access to respondent and organization level data files that do not identify or permit re-identification of individual respondents or Participating Organizations may be granted by AHRQ without the specific authorization of Participating Organizations whose Data are included as part of the data files. Individuals requesting de-identified SOPS data (hereinafter termed "Data Requesters") must submit a Research Abstract Form detailing the research purpose, hypotheses, and methodology for analyzing the data. AHRQ will review all Research Abstract Forms and approve or deny the requests. Data requesters must also sign a Data Release Agreement in which they agree with the following requirements. Data Requesters agree that they: 1) will not use, and will prohibit others from using or disclosing, the de-identified Data except for the purposes specified in their Research Abstract Form; 2) will ensure that the Data are kept in a secured environment and that only authorized users will have access to it; and 3) will limit the use of the Data to the individuals who require access in order to perform activities for the purposes specified in the Research Abstract Form. The de-identified data files may include organizational characteristics (e.g., ownership, bed size, teaching status, etc.), provided the characteristics do not permit re-identification of individual respondents or Participating Organizations.

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Valid purposes for the use of Hospital SOPS de-identifiable Data <u>do not</u> include the use of Data for public reporting, proprietary, commercial or competitive purposes involving those Participating Organizations, or to determine the rights, benefits, or privileges of Participating Organizations.

Release of Hospital-Identifiable SOPS Data for Research Purposes: AHRQ and AHRQ's Contractor, 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.

Individuals requesting hospital-identifiable SOPS data (hereinafter termed "Data Requesters") must submit a Research Abstract Form detailing the research purpose, hypotheses and methodology for analyzing the data. AHRQ will review all Research Abstract Forms and approve or deny the requests. Data requesters must also 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.

Valid purposes for using hospital-identifiable SOPS data <u>include</u> research linking such data to outside datasets. Valid purposes for the use of Hospital SOPS identifiable Data <u>do not include</u> the use of data for public reporting, proprietary, commercial or competitive purposes involving those Participating Organizations, or to determine the rights, benefits, or privileges of Participating Organizations.

- To allow for the release of hospital-identifiable SOPS data for valid research purposes as specified in 10.2, AHRQ and AHRQ's Contractor, 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 14:
 - 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 14), 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 AHRQ and AHRQ's Contractor, Westat, 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 AHRQ's Contractor, Westat. If Option 2 is selected, Participating Organizations will grant authority to AHRQ and AHRQ's Contractor, 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 AHRQ's Contractor, Westat. By selecting Option 2, Participating Organizations entrust the release of their hospital-identifiable SOPS data to Data Requesters approved by AHRQ and AHRQ's Contractor, Westat, per the valid research purposes specified in 10.2.

Option 3: Prohibiting release of all hospital-identifiable SOPS data. If Option 3 is selected, AHRQ and AHRQ's Contractor, Westat, will <u>not</u> release Participating Organization's hospital-identifiable

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SOPS data to anyone, including researchers. Participating Organization indicates it does not want to be offered research proposals to review and will <u>not</u> release its hospital-identifiable SOPS data.

- 10.2.2 At any time, Participating Organizations may request from AHRQ's Contractor, 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.
- 11. AHRQ's Contractor, 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.
- 12. Participating Organization may change or revoke this consent by sending written notification to the AHRQ Surveys on Patient Safety Culture User Network, Westat, 1600 Research Boulevard, Rockville, MD 20850. Requests for changes or revocations must be received within 2 weeks of the current year's data submission deadline to be excluded from the current year's database and all reporting for that year. The request for revocation will not apply to Data already authorized and released prior to receipt of your written request to revoke consent.
- 13. If Participating Organization represents more than one hospital, use the space below to TYPE OR WRITE THE NAME OF EACH INDIVIDUAL HOSPITAL AND ITS ADDRESS, INCLUDING CITY AND STATE which is represented by the Participating Organization and therefore covered under this Data Use Agreement. Attach hospitals additional sheet if necessary.

Add

needed

NAME OF HOSPITAL(S) REPRESENTED	ADDRESS, CITY & STATE
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Select	DUA signature and options for release of hospital-identifiable SOPS Data for research purposes (described in item 10.2.1). <u>SELECT ONE OPTION AND SIGN BELOW.</u> If no option is selected, Option 1 becomes the default.				
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 AHRQ's Contractor, Westat.				
	☐ Option 3: Prohibiting release of all hospital-identifiable SOPS data.				
	Participating Organizati		ed representative consents to the conditions of release of Data under the conditions specified in item 10.2 relevant to the less the default selection.		
	hospitals listed under ite	em 13, and in so doing, enters into	duly authorized to represent the Participating Organization and al to this Data Use Agreement on behalf of the Participating agrees to all the terms specified herein.		
mplete	Name:				
Name, Title,	Title:				
and ∎ Sign	<u> </u>				
9	(Signature)		(Date)		
15.		SS OF PARTICIPATING ORG	GANIZATION CONTACT ation who is the point of contact for this completed DUA.		
Complete is needed	Name of contact (if different from above):				
	Title (if different from above):				
	Title (if different from	Address:			
	Address:		Emaile		
		Fax:	Email:		

David M. Maklan

Senior Vice President, Westat