



**CEDARS-SINAI MEDICAL CENTER**  
**INFORMATION SHEET FOR RESEARCH**

**Title:** A CLUSTER RANDOMIZED CONTROLLED TRIAL COMPARING THE SAFETY ACTION FEEDBACK AND ENGAGEMENT (SAFE) LOOP WITH AN ESTABLISHED INCIDENT REPORTING SYSTEM

**SPONSOR:** THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

**PRINCIPAL INVESTIGATOR:** TERYL NUCKOLS, MD, MSHS

**STUDY CONTACT PHONE NUMBER AT CSMC:** 310-423-1931

**AFTER HOURS CONTACT (24 HOURS):** ANNETTE.BELL@CSHS.ORG

This research study is sponsored by the Agency for Healthcare Research and Quality (AHRQ). AHRQ only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; AHRQ is not providing additional compensation to Cedars Sinai Medical Center or the Principal Investigator for their participation in the study.

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**KEY INFORMATION ABOUT THIS RESEARCH STUDY**

We are seeking your consent to take part in this research study. Your participation in this research is voluntary. If you choose to participate, you can stop at any time. Please consider the following summary, along with the more detailed information provided throughout this consent form.

- The purpose of this study is to understand nurses' opinions toward patient safety issues, medical errors, and event reporting at CSMC.
- The main procedure of this study is to participate in an online survey. If you choose to take part in this study, it will last about 10-15 minutes during working hours.
- All research studies involve some risks. Risks or discomforts from this study may include accidental disclosure of information that could identify you and your opinions.
- You are not expected to benefit from taking part in this research study, but the information learned from this study may help others in the future.
- If you choose not to participate, you will not lose any benefits or rights you would normally have.

Please take time to read this entire form and ask questions before deciding whether to participate in this study. You are encouraged to talk with family members, friends, and/or healthcare providers before you make your decision.

**1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?**

We are doing this study to examine your opinions about patient safety issues, medical errors, and event reporting. We want to know this information so that we can design interventions that make care safer for patients and improve working conditions for nurses.

You are being asked to take part in this research study because you are a nurse on an inpatient unit.

The study will enroll up to 1,980 people in total.

**2. WHAT WILL HAPPEN DURING THE STUDY?**

You will be asked to complete a 10-15 minute electronic survey. The survey will ask questions about patient safety, medical errors, and adverse event reporting. After you are done with the survey, your involvement in the study will be complete.

**3. WHAT ARE THE POSSIBLE RISKS?**

The main risk involved with participating is accidental disclosure of information that could identify you and your opinions.

**4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?**

You should not expect to benefit from taking part in this research study.

**5. WILL I BE INFORMED OF RESEARCH RESULTS?**

You will not be informed of the research results.

**6. WHY WOULD MY PARTICIPATION BE STOPPED?**

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not follow the study procedures.

**7. ARE THERE ANY OTHER OPTIONS?**

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect your job.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to take part in a different study at CSMC or elsewhere, if one is available

## **8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?**

We will do our best to make sure that your information is kept private. However, we cannot guarantee total privacy. A copy of your research consent will be kept on file at CSMC. Your information may be given out if required by law. If information from this study is published or presented at scientific meetings, you will not be identified by name. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

### Protections from Forced Disclosures (Subpoenas) – Confidentiality Statute

To further protect your private identifiable information, the AHRQ confidentiality statute protects your personal information.

This research is covered the AHRQ confidentiality statute, which is similar to a NIH Certificate of Confidentiality. Under this statute, AHRQ-funded research is protected against disclosure of information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this statute cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that the AHRQ confidentiality statute does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide consent to allow the researchers to release it.

The AHRQ confidentiality statute will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.

## **9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?**

You will not be in danger of any illness or injury from this research study. However, should you believe that you are ill or have been injured as a result of your participation, please contact the study team at the phone number listed on page 1 of this consent form.

## **FINANCIAL CONSIDERATIONS**

### Costs of Participation

You will not be charged for your participation in this research study. The Sponsor will cover the cost of all study procedures.

### Compensation for Participating

You will not be paid for taking part in this research study.

### Financial Interest in the Research

The PI and institution have no potential financial conflict of interest with respect to this study.

## **10. WHAT IF I HAVE QUESTIONS OR PROBLEMS?**

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)  
Phone: (310) 423-3783  
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

## **11. CONSENT PROVISIONS**

If you agree to participate in the research, it means that:

- (1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
- (2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
- (3) You have received and understand all of the information you desire regarding your participation in the research study;
- (4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
- (5) You are voluntarily agreeing to participate in this research study;
- (6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights; and
- (7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study.

You can request a copy of this information sheet.

**By completing and submitting this survey, you are agreeing to take part in this research.**