CEDARS-SINAI MEDICAL CENTER

# CONSENT FORM 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 how the implementation of SAFE Loop occurred on your nursing unit.
- The main procedure of this study is one interview. If you choose to take part in this study, you would participate in one interview lasting about 30 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.

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

We are doing this study to explore your opinions about SAFE Loop's implementation on your nursing unit, including what worked well, what did not work well, factors influencing its success, and how you think it could be improved in the future. We want to know this information so that we can better interpret the overall effectiveness of the SAFE Loop at improving incident reporting and lowering medication errors, and potentially improve SAFE Loop and ultimately make care safer for patients.

You are being asked to take part in this research study because you are unit director and/or a nurse on an inpatient unit who participated in SAFE Loop.

## 2. WHAT WILL HAPPEN DURING THE STUDY?

You will be asked to participate in a 30-minute interview that includes questions about implementation of the SAFE Loop on your local nursing unit. After you are done with the interview, your involvement in the study will be complete. The interview will be audio-recorded and transcribed. All information, such as the interview audio-recording and its transcript, will be stored securely on a CSMC server. We may use an experienced, professional third-party contractor to transcribe the audio-recordings. After the transcript is created, the audio-recording will be destroyed to protect your identity. The Cedars-Sinai research team and any contractors that provide audio transcription services will transmit and store data in a secure manner approved by Cedars-Sinai oversight committees.

## 3. WHAT ARE THE POSSIBLE RISKS?

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

The researchers will adhere to institutional protocols for conducting human subjects' research during the COVID-19 pandemic, according to the requirements in place at the time of the interviews.

## 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.

The alternative to participating in this study is not participating in the study.

## 8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that your information collected as part of this study 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 AHRQ.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

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 disclose or use 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 statue 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.

## 10. 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 be entered into a lottery for an iPad.

Financial Interest in the Research

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

## 11. 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.

## 12. CONSENT PROVISIONS

If you sign this form below, 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.

We will give you a copy of this signed and dated consent form**.**

# SIGNATURE PAGE

## Consent Form for Research

**SIGNATURE BY THE PARTICIPANT:** *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

| Name of Participant (Print) | Signature | Date Signed |
|---|---|---|

**SIGNATURE BY THE INVESTIGATOR:** *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

| Name of Investigator (Print) | Signature | Date Signed |
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