Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Evaluating an Innovative Non-interruptive Alert within the Electronic Health Record (EHR) Provider Note to Prescribe Nicotine Replacement Therapy (NRT) in Hospitalized Patients

NCT07164404

Summary: This research study aims to evaluate providers' perceptions and impact of a non-interruptive electronic health record (EHR) alert on nicotine replacement therapy (NRT) prescribing to hospitalized patients who smoke. Consent is being sought for this research, and participation is entirely voluntary. Participation will involve engaging with the EHR alert during patient care and completion of surveys and interviews. Reasonably foreseeable risks or discomforts include minimal time commitment for completing surveys and interviews or interacting with the alert tool. There are no direct therapeutic benefits to participants; however, the research may contribute to improved clinical practices for managing smoking cessation. Alternatives to participating in this study include not engaging with the alert tool, although this would not change the standard care provided.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are an internal medicine resident physician who will interact with this alert during your patient care. The study is sponsored by the South Carolina Clinical and Translational Research (SCTR) Institute. The investigator in charge of this study at MUSC is Ellen Nielsen. The study is being done at one site. Approximately 20 people will take part in this study. Portions of the Ellen Nielsen's salary will be paid by this grant.

B. PROCEDURES

If you agree to be in this study, the following will happen:

You will be randomly assigned to one of two groups, like drawing numbers from a hat.

Group A will receive access to the non-interruptive alert within the EHR the investigational alert, which will become active when admitting a patient who has reported cigarette use to the admitting nurse. Group B will not receive access to the alert and will proceed with usual care.

C. DURATION

Participation in the study will take about three weeks.

D. RISKS AND DISCOMFORTS

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help improve smoking cessation practices for hospitalized patients who smoke and may contribute to the development of better clinical tools and interventions in the future.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 for participation in this study's interviews or surveys.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Results of the proposed research will be disseminated by oral presentation to treating clinicians within Medical University of South Carolina enterprise (hospital care delivery), health services researchers on the University campus, and national professional societies (Society of Hospital Medicine and the American College of Physicians). All findings will be prepared for publication and made available according to NIH standards and policies.

L. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O. MUSC STANDARD PARAGRAPH

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Ellen Nielsen at 443-223-8248***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human

Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

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Signature of Participant Date

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative *(Please print)*

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Signature of Personal Representative Date