INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

ContextCare: A randomized pilot trial of AI-simplified discharge summaries to improve patient comprehension

Study Title:		**ContextCare: A randomized pilot trial of AI-simplified discharge summaries to improve patient comprehension**
Short Title:		ContextCare
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Study Sponsor:		N/A
Study Funding:		N/A

Introduction

You are being invited to participate in a research study. You are invited to participate in this study because you are an adult patient being discharged from Scarborough Health Network and may be eligible for a study about how patients understand discharge instructions. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss with your friends, family or members of your health care team. Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

Conflicts of Interest

We disclose no conflicts of interests related to this study.

Background and Purpose of the Study

When patients leave the hospital, they are given discharge instructions that explain their condition, treatment, medications, and follow-up care. However, many patients find these

instructions difficult to understand, which can lead to confusion, missed appointments, or returning to the hospital.

This study is testing a tool called **ContextCare**, which uses artificial intelligence (AI) to simplify discharge instructions into clear, easy-to-understand language tailored to each patient. The purpose of this study is to determine whether simplified discharge summaries improve patient understanding compared to standard discharge instructions.

What will happen during the study?

Step 1: Baseline

- This study involves one main study visit occurring at the time of hospital discharge at Scarborough Health Network. At this visit, eligibility screening, informed consent, baseline demographic collection, health literacy assessments will be performed.

Step 2: Random Assignment

- You will then be randomly assigned to one of two groups:
  - Standard Care: standard discharge instructions
  - ContextCare: AI-simplified discharge instructions

Step 3: Review of Discharge Instructions

- You will review your discharge instructions.

Step 4: Teach-Back Interview. You will be asked to explain, in your own words:

- Why you were in the hospital
- Your treatment
- Your medications
- Your follow-up plan
- When to seek medical care

Step 5: Follow-up

- Participants will then complete a follow-up assessment 24-48 hours after discharge, conducted by telephone or in person, to evaluate recall of discharge instructions. A 30-day follow-up chart review will also be conducted to collect information on readmissions and follow-up appointment attendance.

Your participation will take approximately 20-30 minutes during discharge.

Use of Artificial Intelligence (AI)

If you are in the ContextCare group, your discharge summary will be processed by an AI tool developed by the research team. All identifying information will be removed before processing. The AI is used only to simplify and organize the information.

Video Recording of Interaction

As part of this study, your discharge interaction and teach-back responses may be video recorded using a standard phone or camera. The recording will focus on the interaction and may include your voice and image. These recordings will be used to:

- Support evaluation of your responses by trained evaluators (PAS)
- Improve consistency and reduce bias in scoring

- Potentially contribute to a secure training database for PAS education and research purposes

See confidentiality section for more information.

Follow-Up Contact (24–72 Hours After Discharge)
We may contact you 24–72 hours after discharge to ask a few follow-up questions about your understanding of discharge instructions. This call will take approximately 5–10 minutes.

Preferred Contact Time (please select one):

Morning (8am – 12pm).	Afternoon (12pm – 4pm).	Evening (4pm – 8pm).	I do not wish to be contacted.

Potential Harms (Injury/Discomfort/Inconvenience)
There are no medical risks to you from participating in this study, but taking part in this study may make you feel uncomfortable. You may refuse to answer questions or leave at any time if you experience any discomfort. There is also a minimal risk that study information may be unintentionally released. The study team will make every effort to keep your information private and secure by storing study data in a secure database, using coded study identifiers, and removing direct identifiers before analysis.

Potential Benefits
You may or may not benefit directly, but possible benefits include better understanding of your discharge instructions. We hope this study may also help improve discharge communication for future patients, leading to safer transitions from hospital to home, more equitable care for patients with different health literacy levels and diverse language or cultural needs, and better understanding of diagnosis, treatment, follow-up care, and return precautions.

Confidentiality
The study investigator and coordinators, (hereby referred to as "study personnel") are committed to respecting your privacy. Confidentiality will be respected and no information that discloses the identity of the participant will be released or published without consent unless required by law. If you agree to join this study, the study personnel may look at your personal health information and collect only the information they need for the study. **Personal health information** is any information that could be used to identify you and may include:

- Your name, telephone number, and hospital medical record number, where applicable;
- Your age, sex, date of birth, diagnosis, treatment plan, discharge summary information, and other information from your electronic health record;
- Your language preference, cultural background, and preferred information format;
- Your responses to the health literacy assessments, teach-back interview, and follow-up assessment; and
- Information about medication adherence, hospital readmission, and follow-up appointment attendance collected for study purposes.

Recorded video of your discharge and teach-back procedure and screening questionnaire responses will also be collected. The videos will be de-identified and not include the study

participant face. They will be stored on an encrypted hard drive accessible only to the study personnel and not used in publications or presentations in a way that identifies you. You may still participate in the study even if you decline recording. The video of your study participation will be kept up to 7 years after completion of study tasks and may be used for future data analysis of other study questions.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. At any point throughout the study, you are free to decline participation and to withdraw early, if you so desire. Doing so will not have any effect on your treatment. Any data collected prior to withdrawal from the study will be retained and kept secure. Data collected prior to withdrawal will be used in future stages of the study. If you withdraw voluntarily from the study, you are encouraged to contact the principal investigator.

Study Results

We may present the findings of this study at a scientific conference and plan to write an article for a scientific journal. No identifying information about you will be disclosed in any presentations or publications related to the study. If you would like to receive the study results once the research is complete, you can request them. You may also request a copy of the published article by contacting the principal investigator.

Potential Costs of Participant and Reimbursement to the Participant

Participating in this study will not result in any costs charged to you, and as such, no reimbursements or compensation will be provided.

SHN Research Ethics Board (REB) Contact

If you have any questions regarding your rights as a research participant and would like to speak to the REB, you may contact Dr. Sherryn Roth at shnreb@shn.ca.

Study Contacts

If you require further information, or have any questions concerning this study, please contact the principal investigator. You will be given a copy of this consent form to keep for your own records.

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Declaration of Consent

By signing this consent form, I acknowledge that:

- The research study has been explained to me, and my questions have been answered to my satisfaction.
- I know that I have the right not to participate and the right to withdraw without affecting the quality of medical care at Scarborough Health Network for me and for other members of my family.
- The potential harms and benefits (if any) of participating in this research study have been explained to me.
- I have been told that I have not waived my legal rights nor released the investigator, sponsor, or involved institutions from their legal and professional responsibilities.
- I know that I may ask now, or in the future, any questions I have about the study.
- I have been told that records relating to me will be kept confidential and that no personal information will be disclosed without my permission unless required by law.
- I have been given sufficient time to read the above information.
- I will be given a copy of the signed and dated consent form.

_____	_____	_____
Name of Participant (print)	Signature	Date

I have explained the study to the above-named participant and discussed the potential risks and benefits (if any) associated with participation in this research study. I have answered all questions asked with respect to this research study.

_____	_____	_____
Name and Position of Person Obtaining Consent	Signature of Person Obtaining Consent	Date of Consent Discussion

Was the participant assisted during the consent process? YES NO

If YES, please check the relevant box and complete the signature space below:

The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

_____	_____	_____
Print Name of Translator	Signature	Date