University of California, Los Angeles

RESEARCH INFORMATION SHEET

Evaluating AI-Generated Plain Language Summaries on Patient Comprehension of Ophthalmology Notes Among English-Speaking Patients at an Academic Center

INTRODUCTION

Prashant D Tailor MD, Irena Tsui MD, Jayanth Sridhar MD and associates, from the Department of Ophthalmology at the University of California, Los Angeles are conducting a research study. This study is being funded by UCLA Department of Ophthalmology. You were selected as a possible participant in this study because *You are eligible to participate because you are an English-speaking adult patient receiving ophthalmology care at the Jules Stein Eye Institute.* Your participation in this research study is voluntary. Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. You are not under any obligation to participate in any research project offered by your clinician.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

WHY IS THIS RESEARCH BEING DONE?

This study aims to assess how well patients understand their ophthalmology notes. To support your understanding of the details in your eye care, we are including an additional summary with some notes. By comparing patient comprehension of these different note formats, we hope to learn more about effective communication between doctors and patients regarding eye health and treatment.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

Participation will take approximately 20-30 minutes in total. This includes the time to review your medical notes and complete a short survey. There is no long-term follow-up required for this study.

If you volunteer to participate in this study, the researcher will ask you to do the following:

If you choose to participate in this study, you will be asked to:

1. *Review your medical notes after your clinic visit. Depending on the group you are assigned to, you may receive either a standard ophthalmology note or a note with an additional summary to support your understanding*
2. *Complete a brief survey to share your feedback on the notes. The survey will ask questions about your understanding of the information, your satisfaction with its clarity and detail, and whether you found it useful in understanding your eye health and treatment.*
3. *Sample survey questions include:*
   How clearly was your diagnosis explained?
   How comfortable do you feel understanding your treatment plan?
   Did the information help you feel informed about your eye health?
4. *One week later a phone call to respond to an additional survey on your visit to include questions on how well you understood the information*

These activities (1-3) will occur during your regular clinic visit at the Jules Stein Eye Institute. The phone call will occur one week later. The additional summary in some notes is part of an effort to explore ways to improve patient understanding.

Randomization is a procedure used to assign research participants by chance to a study group in a clinical trial. It is used to make sure study results are not influenced by the selection of participants in one group as compared to another. In this study, you have a 50% chance of being assigned to one group or another.

-Randomization means that you are assigned to a group by chance (like a flip of a coin). A computer program will place you in one of the groups. Neither you nor the researchers can choose the group you will be in. You will have an equal chance of being placed in any group. You will be randomized into one of the study groups described below.
If you are in Group 1: Participants in this group will receive documentation provided after their clinic visit. This documentation includes the clinical note summarizing the visit and care plan, as typically generated during routine care.
If you are in Group 2: Participants in this group will receive the standard documentation provided after their clinic visit, with an additional summary designed to make the information easier to understand. This summary is reviewed for accuracy before being shared.

ARE THERE ANY RISKS IF I PARTICIPATE?

There are no anticipated risks or discomforts associated with participating in this study. The study involves reviewing your medical notes and answering a brief survey, which should not pose any physical or psychological risk.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You may experience a benefit if the additional summary helps clarify information about your eye health and treatment plan. However, there may be no direct benefit to you

personally, as the study's main purpose is to explore how medical notes can be presented in ways that improve patient understanding.

The results of this research could lead to new methods for presenting medical information that enhance communication between doctors and patients. This may ultimately benefit society by fostering better patient understanding, potentially leading to improved health outcomes and satisfaction with care."

What other choices do I have if I choose not to participate?

Your alternative to participating in this research study is to not participate. If you choose not to participate, your alternative is to continue receiving the standard ophthalmology care provided at the Jules Stein Eye Institute. Your decision will not affect the quality of care you receive.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:
Your personal information will be linked to the research data through a unique study ID. This ID will connect your responses and medical notes to the study while keeping your identity protected. Identifiable information will not be included in study reports or shared outside the research team.

How information about you will be stored:
Your data will be securely stored on an encrypted UCLA server, accessible only to authorized study personnel. Physical records, if any, will be kept in locked cabinets within a restricted access area. Electronic data will be password-protected to maintain confidentiality.

People and agencies that will have access to your information:
Access to your information will be limited to the research team, authorized UCLA personnel for monitoring purposes. UCLA personnel will follow strict confidentiality protocols. Any publications or presentations resulting from this study will not contain identifiable information about you.

The research team, authorized UCLA personnel may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.

How long information from the study will be kept:
Research data from this study will be maintained for at least three years after the study is completed to comply with regulatory requirements. De-identified data may be retained for future research purposes, but no information that could identify you personally will be kept beyond the required retention period.

USE OF DATA FOR FUTURE RESEARCH

Your data, including de-identified data may be kept for use in future research.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The research team:
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: *Prashant Tailor MD; ptailor@mednet.ucla.edu*

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.