INSTRUCTIONS

- This application is intended for behavioral, health services, epidemiological, social science, and education research involving human subjects.

- The UCLA IRB/OHRPP uses this application for all levels of review – Certification of Exemption from IRB review, IRB review using Expedited Review Procedures, and IRB review by the Convened Board. This form should also be used for requests for the UCLA IRB/OHRPP to confirm that IRB review is not required.

- This template identifies supplemental applications that may be required to provide additional information for IRB review of research involving vulnerable populations and/or requiring waivers and alterations of informed consent. The supplements include:

Adults not able to consent for themselves
Children (minors)
Pregnant individuals, fetuses, and/or neonates
Prisoners
Wards
Waivers, waiver of documentation, and alteration of consent, assent, and/or parental permission
HIPAA-covered research

- Additional information that should be appended to the BruinIRB application to support the IRB/OHRPP review of this protocol includes:
    - Recruitment and consent scripts and documents
    - Data collection instruments (surveys, interview protocols, etc.)
    - Federal funding proposals or subcontracts
    - External reviews of project proposals
    - Other supporting documentation as requested by the IRB/OHRPP

- ***Answer all questions***. If a question is not applicable to the research, indicate "n/a".

For questions about how to complete this form, contact the OHRPP staff at gcirb@research.ucla.edu
For email addresses for individual NGIRB or SGIRB staff, see https://ohrpp.research.ucla.edu/staff-directory/

OVERVIEW

Title of Study. This should match the study title provided in the BruinIRB application.

Evaluating AI-Generated Plain Language Summaries on Patient Comprehension of Ophthalmology Notes

Specific Aims. Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed.

To assess the effectiveness of AI-generated plain language summaries (PLS) in improving patient understanding of ophthalmology notes compared to standard notes among English-speaking patients.

Background and Significance. Provide a summary of the background for this study and explain how it will contribute to existing knowledge. State concisely the importance and relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Include citations to relevant scientific or scholarly literature as appropriate. References can be attached to the BruinIRB application.

The proposed study builds on emerging evidence that AI-generated Plain Language Summaries (PLSs) can improve comprehension and satisfaction for individuals without specialized medical knowledge. Findings from our previous study (Tailor et al., 2024, under review; medRxiv preprint) demonstrated the feasibility and effectiveness of LLM-generated summaries in enhancing understanding among non-ophthalmology providers. Utilizing a validated survey developed with the Mayo Clinic Survey Research Center, this study highlighted that PLSs significantly outperformed standard ophthalmology notes (SONs) in terms of perceived clarity, accessibility, and satisfaction. These results indicate a broad potential for PLSs to bridge knowledge gaps in clinical communication.

Informed by these findings, the current study extends the application of PLSs to patients, aiming to address the longstanding challenge of patient comprehension of medical notes. Health literacy is a critical determinant of patient outcomes, influencing adherence to treatment plans, satisfaction, and shared decision-making (McCormack et al., 2017; Berkman et al., 2011). However, standard ophthalmology notes are often laden with medical jargon, limiting their accessibility to patients with low health literacy. The use of AI-generated summaries offers a scalable solution to this issue, providing patient-friendly explanations that can enhance understanding across diverse demographic and educational backgrounds.

This research aligns with the broad, long-term objective of improving patient-centered care through innovations in health communication. By systematically evaluating the impact of PLSs on comprehension and satisfaction, this study addresses a critical gap in the literature and contributes to the field in several ways:

1. **Bridging the Comprehension Gap**: Demonstrating whether PLSs can reduce disparities in health literacy, particularly benefiting patients with lower baseline knowledge.
2. **Operational Feasibility**: Assessing the time burden and accuracy of integrating AI-generated PLSs into routine clinical workflows, providing practical insights for future implementation.
3. **Evidence for Broader Applications**: Generating data that could support the adoption of PLSs in other medical specialties, creating a template for improving interdisciplinary communication and patient engagement.

This study also incorporates rigorous methodologies, including randomized controlled trial design, stratification by health literacy and education level, and validated scoring systems for patient comprehension. The findings have the potential to inform institutional and national guidelines on the use of AI in patient communication, advancing both the science of health literacy and the practice of ophthalmology.

References:

- Berkman ND, Sheridan SL, Donahue KE, et al. Low health literacy and health outcomes: an updated systematic review. *Ann Intern Med*. 2011;155(2):97-107.
- McCormack L, Haun J, Sørensen K, Valerio M. Recommendations for advancing health literacy measurement. *J Health Commun*. 2017;22(2):116-126.
- Tailor P, et al. Evaluating AI-generated plain language summaries for enhancing comprehension of ophthalmology notes: A clinical trial. *medRxiv*. 2024. Available at: https://www.medrxiv.org/content/10.1101/2024.09.12.24313551v1.

Scientific or Scholarly Review. Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review. Click here for additional details. If you want the IRB to consider external scientific or scholarly review, explain the source of the external review, and attach a copy of the review to your BruinIRB application, if applicable.

UCLA IRB has performed the Scientific Review

CHARACTERISTICS OF THE STUDY POPULATION

Number of subjects. State the total number of subjects planned for the study and how many you expect to recruit to obtain this sample size. If research involves multiple groups of participants, specify the number for each (e.g., 50 interview participants, 1,000 survey participants), and the number you would need to recruit for each group.

Alpha=0.05, Power=80% for a 10 percentage point different is 230 per group (460 total)
-For a 5% point difference is 1015 patients per group (2030 total)
-For 7% difference is 498 patients per group (996 total)

Inclusion criteria. Indicate the specific inclusion criteria for enrollment of each of the groups of research participants in this study. If there are any inclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken,* explain the nature of and scientific rationale for the inclusions.

See Protocol 4. Study Population:
4. Study Population

- Inclusion Criteria:
  - Adults (aged 18 years or older).
  - Receiving ophthalmology care at Jules Stein Eye Institute.
  - Able to provide informed consent.
  - Primary language is English.
- Exclusion Criteria:
  - Patients with cognitive impairments that could affect comprehension, such as dementia or intellectual disabilities.

For Ophthalmologists:

- Inclusion Criteria:

Ophthalmologists

- Licensed ophthalmologists affiliated with Jules Stein Eye Institute.

- Actively involved in patient care and note generation for the study.
- Willing to participate in the survey assessing the accuracy, time burden, and satisfaction with AI-generated Plain Language Summaries (PLS).
- Able to provide informed consent.

UCLA students or staff as participants. If either (a) you will have grading or supervisory responsibility for some or all students recruited for the study, or (b) you plan to recruit staff or faculty from your own lab or office, provide justification for recruiting your students/staff. If not applicable, indicate "n/a".

N/A

Exclusion criteria. Indicate the specific exclusion criteria for each of the groups of research participants in this study. If there are any exclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken,* explain the nature of and scientific rationale for the exclusions.

4. Study Population

- Inclusion Criteria For Patients:
  - Adults (aged 18 years or older).
  - Receiving ophthalmology care at Jules Stein Eye Institute.
  - Able to provide informed consent.
  - Primary language is English.
- Exclusion Criteria:
  - Patients with cognitive impairments that could affect comprehension, such as dementia or intellectual disabilities.
  - Prisoners, wards, Patients not able to consent for themselves

For Ophthalmologists:

- Inclusion Criteria:

Ophthalmologists

- Licensed ophthalmologists affiliated with Jules Stein Eye Institute.
- Actively involved in patient care and note generation for the study.
- Willing to participate in the survey assessing the accuracy, time burden, and satisfaction with AI-generated Plain Language Summaries (PLS).
- Able to provide informed consent.
-

Eligibility. How (screening survey, chart review, etc.), when and by whom will eligibility be determined?

Screening will be done prospectively in outpatient clinics at JSEI

Vulnerable Participant Populations requiring submission of additional regulatory supplement(s).
Check all that apply and **attach completed supplement(s) to BruinIRB application.**

☐	Adults not able to consent for themselves
☐	Children (minors)
☐	Fetuses, fetal tissue, and/or neonates
☒	Pregnant individuals
☐	Prisoners
☐	Wards

STUDY DESIGN

☒ **ATTACHMENTS REQUESTED**
Attach your study instruments to your BruinIRB application.
- Include interview protocols/outlines, focus group protocols, survey instruments, intervention materials.
- Ensure that names of your documents (e.g., Parent interview) match your description below.
- For complex study designs, develop a flow chart of study procedures.

Study methods and procedures. Describe in chronological order how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures.

- Explain who will conduct the procedures, where and when they will take place.
- Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.
- State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).
- If your research involves participant observation, explain where the observations will occur, including whether locations are public/private, indicate who and what you are proposing to observe, describe the information that will be recorded in the research records (indicate whether data will include personally identifiable information), and outline the procedures for collecting data (written notes, audio/video recording).
- Describe alternatives to participation, if any.
- Use sub-headings to organize and describe separate procedures if applicable to subsets of the study population.

(describe study methods and procedures)

See Protocol (Study Protocol Sections: 5-13)

No audio or video recording; Participants are not observed the patients will be able to ask study personnel for clarification if they have questions on the survey. The patients will fill out the survey and hand them to study personnel. Alternatives is care as normal.

1. Procedures for the Follow-Up Call (Detailed in the Protocol document):
o The follow-up call will be conducted by a trained member of the research team (e.g., a research coordinator or resident).
o Calls will occur approximately seven days after the initial clinic visit, at a time convenient for the participant, as determined during the consent process.
o The team member will confirm the participant's identity before proceeding with the survey, ensuring compliance with privacy regulations.
o The call will last approximately 10–15 minutes, during which the participant will respond to structured and open-ended questions related to their comprehension of the information provided during their visit.
2. Survey Content (Detailed in Study Protocol document Pages 10-11)
o The follow-up survey will assess the participant's understanding of their diagnosis, treatment plan, and follow-up instructions. Questions will be open-ended to elicit detailed responses but scored based on a standardized rubric to ensure consistency and reliability in data analysis.
o Example questions include:
Diagnosis Comprehension: "In your own words, can you explain what your diagnosis is?"
Treatment Plan Comprehension: "What treatment steps did your doctor recommend in the note?"
Follow-Up Instructions: "What actions, if any, were recommended for you to take after this visit?"
- The survey will also assess participants' confidence in their understanding and perceived clarity of the information provided.

Purpose of Medical Record Access:
o The waiver is requested to allow limited access to medical records for the purpose of identifying potential participants who meet the study's inclusion criteria within the participating clinics.
o Additionally, access is needed to obtain research data, specifically patient demographics, diagnosis, treatment plans, and follow-up instructions documented in the Standard Ophthalmology Note (SON), for analysis and comparison with the AI-generated Plain Language Summaries (PLS)..
Supplement for HIPAA-Covered Research:
o As noted, a completed HIPAA supplement has been uploaded in the study history section. This document outlines the specific measures in place to protect PHI during the study.

Collaborative Research. If non-UCLA-affiliated personnel or institutions are collaborating in the research describe the nature of the collaboration. If UCLA will serve as reviewing IRB (aka Single IRB or "SIRB"), explain.

After submission of your BruinIRB application, the UCLA IRB/OHRPP will provide instructions – when applicable - for how to provide the information required for UCLA to formalize the necessary reliance agreements and to complete IRB review for the relying sites. Click here for more information about UCLA serving as reviewing IRB.

N/A

Deception or Withholding of Information. Reference: OHRPP Guidance Deception or Incomplete Disclosure,
If the study will involve any type of deception or incomplete disclosure to participants, respond below to provide the requested information.

- Describe the information that will be withheld from, or misinformation that will be provided to participants.
- Explain why it is necessary to involve deception in the research.
- Describe plans for de-briefing participants after study participation or explain and justify why no de-briefing will be provided.
- Explain why the research could not practicably be carried out without the alteration of consent.
- Attach your debriefing script to your BruinIRB application.

If your research does not involve deception or incomplete disclosure, indicate "n/a".

N/A

Existing data/specimens. If the proposed research includes use of existing data/specimens, describe how data/specimens will be acquired. Specify the source of the data/specimens, explain what personally identifying information (PII) is included with the data/specimens. Explain if data are publicly available.

- Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective.
- Describe the data and/or specimens and indicate the original collection dates.
- Indicate the approximate number of data records and/or specimens to be collected.
- Attach to your BruinIRB application any data abstraction tools or lists with the data elements to be collected.

If your research does not involve use of existing data/specimens, indicate "n/a".

N/A

Statistical plan. Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined. For qualitative research, briefly describe how qualitative data will be analyzed.

(describe statistical plan)

See Protocol 8; 10 Data Collection and Analysis
10. Data Collection and Analysis

- Patient Survey The survey will contain several components:
  - Comprehension Questions: A set of 5-point Likert scale questions to assess patients' understanding of their diagnosis, treatment plan, and overall health condition as described in the note.

- Satisfaction and Usefulness Assessments: Likert scale questions to determine patients' satisfaction with the level of detail, clarity, and usefulness of the information.
- Demographic Information: Questions on age, gender, education level, and previous ophthalmology experience will be included to characterize the study population.

- Ophthalmologist Survey
- Follow Up Patient Survey

Data Analysis Data collected will be analyzed using statistical methods:

- Independent t-tests or Mann-Whitney U tests will be used to compare comprehension and satisfaction scores between the control and intervention groups.
- Chi-square tests will be used for categorical variables, such as satisfaction ratings.
- Multivariable regression will adjust for potential confounders, including age, education level, and baseline health literacy, to identify independent predictors of improved comprehension.
- Subgroup Analysis: Analysis will also be conducted to determine whether certain subgroups (e.g., low health literacy) benefit more significantly from the PLS intervention.
- Stratification by age, level of education and complexity of visit (level of service/billing)

13. Expected Outcomes

- Primary Outcome: Improvement in patient comprehension of ophthalmology notes, as measured by the survey's comprehension questions.
- Secondary Outcomes:
  - Patient Satisfaction: Higher satisfaction scores among patients receiving SON + PLS compared to those receiving the SON alone.
  - Comprehension Gap Reduction: Reduction in the comprehension gap between patients with low and high baseline health literacy, indicating that the PLS is particularly beneficial for those with limited medical knowledge.
  - Time Efficiency: Evaluation of the time burden for ophthalmologists reviewing PLSs, aiming for minimal disruption to clinical workflow.
  - Inbasket message rates
  - Medication fill compliance rates
  - Ophthalmologist satisfaction
  - LLM summarization Error rates
  - Error rates for ophthalmologist overreads
  - Improved Objective Patient Comprehension: higher scores 1 week later for patients with the PLS

IDENTIFICATION, RECRUITMENT, AND SCREENING

☐ **ATTACHMENTS REQUESTED**
Attach your recruitment and screening documents to your BruinIRB application, including flyers, letters, email text, scripts. **Click here for UCLA guidance on recruitment materials** .

Recruitment methods. Check all that apply to identify your recruitment methods.

☐ Recruitment letters, emails, or text messaging
☒ Direct recruitment (e.g., contact between study team and potential subjects in person, by phone or internet)
☐ Advertisements, flyers, internet posting
☐ Online platform such as mTurk, Prolific, Dynata, Cloud Research, etc.

- ☐ Review of publicly available records *(indicate the source below)*
- ☒ Review of medical records
- ☐ Review of other records *(indicate the source below)*
- ☐ Participant pool for which potential research participants have agreed to future contact.*
- ☐ Potential study participants are identified from another IRB approved study or screening protocol.*
- ☐ Referrals (e.g., referrals from non-investigator healthcare providers, participants referring other persons, etc.)
- ☐ Other

Indicate the source of records and/or the related IRB number(s) for the recruitment methods selected above.

Patients will be recruited when they present to their normal scheduled JSEI outpatient appointments based on the clinic schedule.

- **Source of Records/Participants**: Patients will be identified during their routine visits to the Jules Stein Eye Institute.
- **Recruitment Process**: Eligible patients will be approached directly by a member of the study team at the beginning of their clinic visit. The team will provide information about the study and obtain written informed consent using a standardized script to ensure consistency and transparency.

If needed, further details can be added regarding the recruitment process or justification for the selected methods.

Description of recruitment and screening. Explain below how subjects will be identified, recruited, and screened.

- Include information about **how, when, where, and in what setting** these processes will occur.
- Identify who (by position or role, not name) will approach and recruit subjects, and who (by position or role, not name) will screen them for eligibility.
- If existing records will be accessed or obtained for recruiting and screening procedures prior to enrollment, describe the source and contents of the records used and whether it will be retained as part of the study data.
- Note: If screening questions will be used to determine eligibility, they should be limited to those required to confirm eligibility.
- If you will be directly recruiting potential participants who are your patients, students, laboratory workers or others with whom you have a **relationship of authority or unequal power,** describe what measures you will put in place to avoid those approached from feeling pressured or unduly influenced to participate in the study.
- If consent will be obtained for any of the screening procedures, explain.
- If the research involves physicians/clinicians recruiting their own patients, avoid conflating the research with clinical care/services.

(describe recruitment and screening)

Click or tap here to enter text.

CONSENT FOR STUDY PARTICIPATION

☒ **ATTACHMENTS REQUESTED**
Attach your consent documents to your BruinIRB application.
Click here for UCLA template consent documents and standard language .

Method(s) of Informed Consent. Select the consent methods you will use. Check all that apply.

- ☐ Obtain signed consent (Participant or Legally Authorized Representative)
- ☐ Obtain consent online* (Waive written documentation of consent)
- ☒ Obtain verbal consent* (Waive written documentation of consent)
- ☐ Obtain signed parental permission
- ☐ Obtain signed assent from children/adolescents
- ☐ Obtain verbal assent from children/adolescents or adults unable to consent
- ☐ Waive consent and/or parental permission*
- ☐ Waive assent / Assent is not appropriate*

**If selected, complete and attach to your BruinIRB application the applicable supplement to provide information to justify the waiver(s): Supplement: Waiver of Documentation of Consent or Waiver of Informed Consent*

If different groups of participants will have different consent methods, explain.

N/A

Consent Process Description. Provide a step-by-step description of the consent process, including:

- Outline the personnel involved, and the methods to be used.
- Indicate the type of setting(s) in which the consent process will be conducted – if the setting is not private, describe the measures to protect confidentiality.
- Describe the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.
- Specify the length of time subjects are given to decide whether they wish to participate in the study.
- Explain how you will assess whether subjects understand the information conveyed during the consent process.
- If applicable, explain if permission will be obtained from individuals other than parents, and if so, how you will determine that the individual providing permission has the authority to do so.

Identification of Subjects
Subjects will be identified during routine ophthalmology clinic visits at the Jules Stein Eye Institute. Recruitment will target adult patients who meet the inclusion criteria (English-speaking, 18 years or older, able to provide informed consent). Patients will be identified through physician's schedules of physicians who have agreed to participate in the study within their clinics. Research personnel will identify potential participants based on their clinical encounters and familiarity with the inclusion criteria, based on medical records for the sole purpose of recruitment.

Recruitment Process

- **How and Where**: Recruitment will take place in person at the Jules Stein Eye Institute during patients' scheduled clinic visits.

- **When**: Patients will be approached at the start of their visit, either in the waiting room or during the intake process, before their consultation with the ophthalmologist.
- **Who Will Approach Subjects**: A trained member of the study team (e.g., research coordinators, medical students, residents, fellows, or staff physicians) will initiate the recruitment process. These individuals will be trained to explain the study objectives and procedures using a standardized script to ensure clarity and consistency.

Screening for Eligibility

- **Who Will Screen**: Screening for eligibility will be conducted by research coordinators or trained clinical team members.
- **Screening Process**: Eligibility will be determined through verbal confirmation of the inclusion and exclusion criteria. Screening questions will be limited to those necessary to confirm eligibility, such as age, language proficiency, and cognitive ability (to exclude individuals with cognitive impairments affecting comprehension).
- **Screening During Consent**: Informed consent will also confirm eligibility criteria. Any additional clarification required will occur during this process.

Avoiding Undue Influence

To mitigate any undue influence or pressure:

- Recruitment will emphasize the voluntary nature of participation and assure patients that their decision to participate or decline will not affect their clinical care in any way.
- Study team members will explicitly state that declining participation will not impact their relationship with their care provider or the care they receive.

Clinical vs. Research Distinction

When a physician who has an existing clinical relationship with a patient is involved in recruitment, the research team member (not the treating physician) will conduct the initial approach. This ensures a clear distinction between the patient's clinical care and the research study.

Use of Records

Existing patient records will not be accessed prior to recruitment or screening. No data will be retained from non-participants. For participants, only the data explicitly collected as part of the study will be included in the research database.

Consent for Screening

Informed consent will be obtained before any study-related procedures, including screening for eligibility. The consent process will use a standardized script and informed consent form reviewed and approved by the IRB.

This structured approach ensures compliance with ethical standards while maintaining patient autonomy and minimizing bias during recruitment and screening.

Parent Permission and Child/Adolescent Assent Processes. If research involves minors, provide a step-by-step description of the processes for obtaining parent permission and child/adolescent assent.

If research does not involve minors, indicate "n/a".

n/a

Cultural Considerations. Check all that apply to the population(s) with which this study will be conducted.

☐ Participants may be illiterate or insufficiently literate to be able to comprehend a conventional written informed consent form.

☐ The participants may be reluctant or unwilling to sign a written informed consent form.
☐ The husbands make decisions for their wives.
☐ Elders make decisions for younger adult family members.
☐ Elders make decisions for their community.
☐ It is considered impolite to refuse a request.
☐ People are fearful of refusing requests that they regard as coming from authorities.
☒ **None of the above are applicable to this study.**

If any of the above items are applicable to this study, indicate the steps that you will take to ensure voluntary participation after providing the study information, and if applicable, any planned involvement with the community regarding the consent process.

Click or tap here to enter text.

INFORMATION ABOUT THE STUDY DATA

Data related to health or mental health care. Check all that apply.
☐ Obtained from a medical or clinical record.*
☒ Created or collected as part of health or mental health care.*
☐ Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals.*
☐ Research data will be entered into the participants' medical or clinical record.*
☐ None of the above.

Responses with * require completion of the HIPAA-COVERED RESEARCH SUPPLEMENT

Indicate all identifiers that may be **accessed or included in the research records** for the study:

☐ Names	☐Health Plan Numbers
☒ Dates	☐ Account Numbers
☒ Age (if over 89 years)	☐ License/Certificate Numbers
☐ Postal Address	☐ Web URLS
☐ Phone Numbers	☐ IP Address Numbers
☐ Fax Numbers	☐ Biometric Identifiers (including finger and voice prints)
☐ Email Address	☐ Facial Photos/Images
☐ Social Security Number*	☐ Any Other Unique Identifier (this does not include the code assigned by the investigator to identify the data)
☒ Medical Record Number	

None of the above ☐

***If social security numbers will be collected explain why they are necessary, how they will be used, how they will be protected and how long they will be retained.**

Click or tap here to enter text.

DATA SECURITY

Data security plan. Describe your data security plan by either providing a narrative response or attaching a document that addresses the following:

- Indicate **how data will be stored and secured** including paper records, electronic files, audio/video tapes, specimens, etc. Specify how the **code key** will be securely maintained, as applicable.
- **Data on portable devices (e.g., laptops, external hard drives)**: Specify whether personal or private identifiable data will be stored on portable devices. If so, **provide the rationale** for storing the identifiers on the device. Note: only the minimum data necessary should be stored on portable devices.
- Describe **any additional steps** taken to assure that identities of participants and any personal or private information are kept confidential.
- If personal identifying information will be removed or destroyed or the data/specimens will be coded, describe the process for removing and destroying the personal identifying information or for coding the information, and indicate who will perform the task.
- **If video or audio recordings will be made as part of the study,** disposition of these recordings should be addressed here and in the consent document(s).
- **Internet research:** If data will be collected, transmitted, and/or stored via the internet, indicate the measures that will be taken to ensure security of data transmitted over the internet.
- **If you have a data security plan, attach it to your BruinIRB application.**

Storage and Security

- **Electronic Data**: All electronic data, including survey responses and study records, will be stored on a secured, UCLA-encrypted laptop or Box. The laptop will be kept in a secure, locked room when not in use. Access to the laptop will be restricted to authorized study personnel only.
- **Paper Records**: Any paper records, such as signed consent forms, will be securely stored in a locked file cabinet located in a secured room at the Jules Stein Eye Institute. Only authorized personnel will have access to the room and the cabinet.
- **Data Identifiers**: No data identifiers will be used instead a unique encrypted ID will be created.

Portable Devices

- The only portable device will be the onsite UCLA secured and encrypted laptop (kept in a secure room) that will be used to run the local model.

Confidentiality Protections

- **Data Handling**: The use of MRNs ensures minimal use of personal identifying information. All MRNs will be stored in encrypted files, and access will be restricted to study personnel with specific data analysis roles.
- **Local Large Language Model (LLM) Use**: All LLM processing (e.g., for generating Plain Language Summaries) will be conducted locally within the UCLA intranet. No data will leave the institution or be transmitted via external networks. Only UCLA-secured and IRB-approved devices will be used for LLM operations.

Removal and Destruction of Identifiers

- Upon completion of the study or when no longer required, all identifiers will be securely destroyed. Paper records will be shredded, and electronic records will be deleted using UCLA-approved secure deletion methods.

Retention and Final Disposition

- Study data, including unique identifier-linked files, will be retained on the secured laptop for the duration required by UCLA policy and IRB guidelines (e.g., three years post-study completion). Upon the end of this retention period, data will be securely deleted or archived in compliance with institutional requirements.

☒ **In event of data security breach.** Provide your assurance that if there is a data security breach for this study, you will notify the IRB and your department's IT Compliance Coordinator. See UCLA Policy 420 for more info.

FUTURE USE OF DATA AND/OR SPECIMENS

Future use. Indicate if the data will be stored for future use after this study is completed. Check all that apply.

☒ Stored for possible future research
☐ Add to existing repository
☐ Not applicable, data will not be stored for future use
☐ Use to create a bank or repository at UCLA. *If you will create a bank or repository, attach to your BruinIRB application your Standard Operating Procedures (SOPs). Click here to review related UCLA IRB/OHRPP guidance and requirements.

Retention of personal or private information after the study is completed. If personal or private information will either be kept with the data and/or specimens, or data or specimens will be coded, provide the following information.

- Describe how and where data and/or specimens will be stored, including the security measures for preventing un-authorized access.
- If personal or private information and/or codes will be maintained, explain how the information will be securely handled and stored, how will you assure confidentiality, and who will have access to the identifiers and/or codes.
- Explain whether the materials will be de-identified, and if so, when, how and by whom.
- If data include audio or video recordings, explain whether transcriptions include identifiers and explain whether recordings will be destroyed or modified to eliminate the possibility that study participants could be identified.

N/A

Distribution Rules. If data and/or specimens will be shared for future research, describe the criteria used to determine the adequacy of requests to obtain data and/or specimens (e.g., the type of researchers that will be eligible to receive data and/or specimens).

If data are to be shared for future research, the following criteria and procedures will be applied to determine the adequacy of requests to access the data:

1. **Eligibility of Researchers**:
    - Only researchers affiliated with academic or research institutions, healthcare organizations, or other reputable entities engaged in scientific research will be eligible to request data access.
    - Researchers must demonstrate that their proposed use of the data aligns with the purpose of advancing scientific knowledge and patient care, with a focus on health communication, patient comprehension, or related fields.
2. **Criteria for Requests**:
    - Requests must include a detailed research proposal outlining the objectives, methodology, and anticipated benefits of the proposed study.
    - Proposals must specify how the data will be used, stored, and protected to maintain confidentiality and comply with applicable regulations (e.g., HIPAA, UCLA policy).
    - Researchers must provide evidence of IRB approval or exemption for their proposed research.
3. **Data Sharing Agreements**:
    - Prior to data sharing, researchers must sign a data use agreement (DUA) that specifies the terms and conditions of access, including:
        - Prohibition of attempts to re-identify participants.
        - Restrictions on sharing or redistributing the data to third parties.
        - Requirements for secure storage and timely destruction of data after study completion.
4. **Approval Process**:
    - Requests will be reviewed by the principal investigator (PI) and, if necessary, an advisory committee to ensure alignment with ethical standards and the study's objectives.
    - The PI reserves the right to deny requests that do not meet the criteria outlined above or pose potential risks to participant confidentiality.
5. **De-identification**:
    - All shared data will be fully de-identified prior to distribution, with all direct and indirect identifiers removed in compliance with HIPAA and UCLA guidelines.
    - A unique study ID will replace identifiers, and no code keys linking data to individual participants will be shared.
6. **Purpose and Oversight**:
    - Data sharing will prioritize research that aligns with the study's aims, such as improving health literacy, enhancing patient comprehension, or advancing AI applications in medicine.
    - The PI will monitor adherence to the data use agreement and ensure compliance with institutional and regulatory policies.

By implementing these rigorous criteria and oversight processes, data sharing for future research will be conducted in a manner that safeguards participant confidentiality while promoting valuable scientific advancements.

PRIVACY AND CONFIDENTIALITY

Privacy. How will the investigator maintain privacy in the research setting(s)? (e.g., interviewing participant in a room or area where conversations cannot be overheard by others).

To maintain participant privacy in the research setting:

1. **Recruitment Setting**: Recruitment and consent discussions will occur in private or semi-private spaces within the Jules Stein Eye Institute, such as exam rooms or consultation areas, where conversations cannot be overheard by others.
2. **Data Collection**:
    - Surveys or interviews will be conducted in private areas to ensure confidentiality.
    - Participants will be given the option to complete surveys electronically on a secured device in a private setting or via a paper format that they can complete without others present.
3. **Communication**:
    - Any communication with participants (e.g., recruitment, follow-up questions) will occur through secure and private channels, such as face-to-face interactions or encrypted email, if applicable.
    - No discussions regarding the study will take place in shared or public areas to avoid accidental disclosure of participant information.
4. **Study Team Training**: All research personnel will be trained to respect participant privacy during interactions, ensuring that sensitive discussions occur only in private spaces and that no personal information is inadvertently shared.

Confidentiality: If the protocol will collect and maintain identifiable data, explain how the planned safeguards to maintain confidentiality of identifiable data and data security are appropriate to the degree of risk from disclosure.

The study will collect and maintain identifiable data, using a unique study ID assigned to each participant to track and manage participant information. Medical record numbers (MRNs) will not be used for data tracking. The following safeguards will ensure the confidentiality of identifiable data, appropriately addressing the degree of risk from disclosure:

Data Collection and Storage

- **Electronic Data**: Data will be stored in encrypted files on a secured, UCLA-encrypted laptop, kept in a locked room at the Jules Stein Eye Institute. Access to the laptop will be restricted to authorized study personnel, and all data will be password-protected.
- **Paper Records**: Any paper records, including consent forms, will be securely stored in a locked file cabinet within a secured room at the Jules Stein Eye Institute. Access to the cabinet will be restricted to authorized personnel.
- **Data Access Controls**: Access to both electronic and paper records will be limited to study personnel who require it for their role, such as data entry or analysis.

Data Transmission and Use

- **Local Data Processing**: All data processing, including the generation of Plain Language Summaries (PLSs), will be conducted locally on UCLA-approved devices within the institution's secure intranet. No identifiable data will leave the UCLA network or be transmitted externally.

- **De-identification for Analysis**: Identifiable information will be replaced with a unique study ID before analysis. The code key linking participants to study IDs will be stored in a separate, encrypted file on the secured laptop, accessible only to authorized personnel.

Safeguards Against Disclosure

- **Encryption**: All electronic files containing identifiable data will be encrypted to protect against unauthorized access. The encryption meets or exceeds UCLA and HIPAA compliance standards.
- **Physical Security**: The laptop and paper records will be secured in locked rooms with controlled access. Only study personnel with key authorization will have entry.
- **Data Retention and Destruction**: Identifiable data will be retained only for the duration required by UCLA policy and IRB guidelines (e.g., three years post-study completion). After this period, data will be securely destroyed using UCLA-approved methods (e.g., shredding for paper records, secure deletion for electronic files).

These planned safeguards are proportional to the degree of risk posed by the collection and maintenance of identifiable data, ensuring participant confidentiality while allowing the study to achieve its objectives.

State mandated reporting. Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse), ethically requires action (e.g., suicidal ideation) or is a reportable disease? ☒ No ☐ Yes

If yes, explain below and include a discussion of the reporting requirements in the consent document. For more information see UCLA OHRPP Guidance: Reporting Suspected Abuse or Neglect of Children, Elderly Individuals, and Dependent Adults, Reporting of Diseases and Conditions Identified in the Course of Research, and Research Protocols and Risk of Suicide

Click or tap here to enter text.

☐ **Certificate of Confidentiality.**
Check here if you plan to apply for a Certificate of Confidentiality for non-federally funded research. For more information see https://ora.research.ucla.edu/OHRPP/Documents/Policy/6/COC_NonFederallyFunded.pdf .

RISK/BENEFIT ASSESSMENT

Risk Assessment. Indicate the level of risk involved with this study. If there are multiple groups or phases involved with this study indicate the highest level of risk.

☒ **Minimal risk.** Click here for OHRPP tip sheet on Minimal Risk.
Minimal risk is defined *as the probability and magnitude of harm anticipated in the research are not greater than those encountered in daily life (i.e., daily lives of the general population) or during performance of routine physical or psychological examinations or tests.*

☐ **Greater than minimal risk.**

Benefits to participants. Describe any potential **direct** benefits (psychological, social or other) to study participants.
If participants will not directly benefit from their participation, state this. *Note that payment for participation is not considered a benefit.*

Participants in this study may experience the following potential direct benefits:

1. **Improved Understanding of Medical Information**: Participants in the intervention group receiving AI-generated Plain Language Summaries (PLSs) may gain a clearer and more accessible understanding of their ophthalmology notes. This improved comprehension could enhance their knowledge of their diagnosis, treatment plan, and follow-up instructions, empowering them to take an active role in managing their eye health.
2. **Enhanced Patient-Provider Communication**: By improving the clarity and accessibility of medical information, the study may facilitate more effective communication between participants and their ophthalmologists, potentially reducing the need for clarification and follow-up questions.
3. **Reduction in Health Literacy Barriers**: Participants with lower baseline health literacy may particularly benefit from the simplified language and explanations provided in the PLSs, helping to bridge comprehension gaps.
4. **Psychological Benefits**: Increased understanding of their medical condition may reduce anxiety or uncertainty about their health and treatment plan, contributing to greater confidence and peace of mind.

Participants in the control group may not directly benefit from the study but will still receive the standard of care, including comprehensive ophthalmology notes. While there is no guarantee of direct benefits, insights from this study may contribute to future improvements in patient-centered care and health communication for others.

Benefits to society. Describe the potential benefits to society including the importance of the knowledge to be gained.

This study has the potential to deliver several important benefits to society, including:

1. **Advancing Health Literacy**: The findings may demonstrate the effectiveness of AI-generated Plain Language Summaries (PLSs) in bridging comprehension gaps, particularly for individuals with lower health literacy. By improving accessibility to complex medical information, this research supports broader efforts to enhance health literacy, which is a critical determinant of patient outcomes and healthcare equity.
2. **Improving Patient Outcomes**: By empowering patients to better understand their medical conditions and treatment plans, the study may contribute to improved adherence to treatments, better self-management of health, and ultimately, better health outcomes. These benefits could extend beyond ophthalmology to other medical fields.
3. **Enhancing Patient-Centered Care**: The study aligns with the growing emphasis on patient-centered care by addressing a key barrier: the complexity of medical communication. Findings may inform best practices for incorporating simplified, patient-friendly language into clinical workflows, leading to more inclusive and effective healthcare delivery.
4. **Scalable Application of AI in Medicine**: The study will provide evidence on the feasibility, accuracy, and utility of using AI-generated summaries in a clinical setting. This could pave the way for the adoption of similar technologies across other specialties, making healthcare communication more efficient and accessible on a larger scale.

5. **Reducing Disparities in Healthcare**: By identifying the potential benefits of PLSs for individuals with lower baseline health literacy, the study supports efforts to reduce disparities in healthcare access and understanding, contributing to a more equitable healthcare system.
6. **Knowledge Dissemination**: The insights gained from this research will contribute to the scientific literature on health communication, AI applications in medicine, and patient-centered care. The findings may inspire future research and inform policies aimed at improving communication in diverse healthcare settings.

By addressing a critical gap in patient comprehension and contributing to the broader adoption of AI in healthcare, this study has the potential to significantly improve the quality, accessibility, and equity of medical care for society at large.

Potential risks/discomforts. Indicate potential risks/discomforts, if any, associated with each intervention or research procedure, and discuss any measure that will be taken to minimize risks.

- A risk/discomfort is a potential harm associated with the research that a reasonable person would consider important in deciding whether to participate in the research.
- Risks can generally be categorized as physical, psychological, sociological, economic, and legal.
- The information provided should be reflected in risks section of the informed consent documents.
- *If there are no anticipated risks or discomforts, indicate n/a.*

Potential Risks/Discomforts

1. **Psychological Risks**: Participants may feel frustration or anxiety if notes or summaries are unclear.
    - **Mitigation**: Ophthalmologists will review PLSs for accuracy, and participants can ask their physician for clarification.
2. **Sociological Risks**: Participants may worry their responses could affect their care.
    - **Mitigation**: Participants are assured their care will not be impacted.
3. **Data Confidentiality Risks**: Risk of unauthorized access to identifiable data (e.g., MRNs).
    - **Mitigation**: Data is encrypted, stored securely, and de-identified before analysis. All processing occurs on UCLA-secured devices onsite.
4. **Misunderstanding Risk**: Participants may misinterpret the PLSs.
    - **Mitigation**: PLSs are reviewed for inappropriate and incorrect information from the physician who saw the patient prior to use, and participants are encouraged to discuss questions with their physician.

No physical, economic, or legal risks are anticipated.

Risk/Benefit Analysis: Indicate how the *risks to the participants are reasonable in relation to anticipated benefits,* if any, to participants and the importance of the knowledge that may reasonably be expected to result from the study.

The benefits of this study far outweigh the minimal risks to participants:

1. **Minimal Risks**: The risks include psychological discomfort (e.g., frustration with unclear information), sociological concerns (e.g., fear of care impact), and data confidentiality risks. These are effectively mitigated through stringent measures, such as encrypted data storage, de-identification, and thorough review of PLSs by ophthalmologists to ensure accuracy.

2. **Substantial Benefits to Participants**:
    - **Direct Benefits**: Participants in the intervention group are likely to experience improved comprehension of their medical notes, enhanced ability to manage their eye health, and reduced anxiety about their condition due to clearer communication.
    - **Empowerment**: Patients with low baseline health literacy stand to gain the most, bridging gaps in understanding and fostering greater confidence in their healthcare decisions.
3. **Broader Impact**:
    - This research has the potential to transform healthcare communication, paving the way for the widespread use of AI-generated summaries to improve patient outcomes.
    - It addresses critical health literacy disparities, advancing equity in healthcare delivery.
    - The knowledge gained will benefit not just the study participants but also future patients and healthcare providers, informing best practices in patient-centered care.

In conclusion, the minimal and well-managed risks are greatly outweighed by the potential for meaningful benefits to participants and the significant societal value of the knowledge this study aims to generate.

FINANCIAL CONSIDERATIONS FOR PARTICIPANTS

Payment. Describe method and amount of any payments or remuneration (e.g., course credit) made to participants.
If there are multiple study visits for which participants are paid, indicate if payments are pro-rated and when payment will be made.

None

Costs. Describe any research-related costs for which participants may be responsible.

None

ADDITIONAL INFORMATION

If there is any additional information that you want to communicate about the study, provide that information here.

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