Study Title: The Support, Educate, Empower (SEE) Program Glaucoma Coaching Trial

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Informed Consent Document IRB Approval Date: 11/20/2023

CONSENT TO BE PART OF A RESEARCH STUDY

PART 1 OF 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study title:	Support, Educate, Empower: The SEE Personalized Glaucoma Coaching Trial
Company or agency sponsoring the study:	The National Institutes of Health

1. KEY INFORMATION ABOUT THIS STUDY

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research will test whether personalized glaucoma coaching improves overall adherence to eye drop medications compared to enhanced standard care. The research will enroll glaucoma patients in a randomized controlled clinical trial to assess this outcome. Your eye health information, including your visual field and visual acuity will be collected for this research study. If you have had a recent (within the last 12 months) visual field that is reliable, you will not need to repeat your visual field test to participate in this study.

This study involves a process called randomization. This means that the type of glaucoma education you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not choosing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, the risk of physical injury is unlikely; you may experience minor discomforts from routine eye examinations and tests. This study may not offer any benefit to you now but may benefit others in the future by helping to create a better educational program for other glaucoma patients.

We expect the amount of time you will participate in the study will be 6 months unless you choose to end your participation sooner.

You can decide not to be in this study. Alternatives to joining this include simply continuing your care with your ophthalmologist.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

You have been asked to participate in this research study because you have been diagnosed with glaucoma, are taking at least one glaucoma medication and have told us that you have had a hard time remembering to take all of your glaucoma medications at some point.

This research will test whether the Support, Educate, Empower (SEE) personalized Glaucoma Coaching Program, compared to standard care with your physician along with additional written glaucoma education materials, improves adherence to glaucoma medications through a randomized clinical trial.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To be eligible for this research study you must:

- Be at least 18 years of age or older
- Have a diagnosis of glaucoma, glaucoma suspect or ocular hypertension
- Currently be taking 1 or more glaucoma medications
- Have difficulty remembering to take your glaucoma medication(s)
- Be able to administer your glaucoma medications yourself
- Have a landline or cell phone
- Did not decline participation after receiving study information letter

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

3.2 How many people (subjects) are expected to take part in this study?

A combined total of 230 participants from the Kellogg Eye Center and the Henry Ford Health System will be asked to participate in this trial.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Baseline Visit: The first visit which will take approximately 60 - 90 minutes. During this visit informed consent will be obtained in a private space. Once informed consent is obtained the following study activities will take place:

- A research associate will check your eye pressure.
- You will be asked to fill out surveys on a computer tablet.
- We will measure your visual acuity. Visual acuity is measured by your ability to identify letters or numbers on a standard eye chart.

- If you have not had a reliable visual field test in the last twelve months, we will check your visual field. Your visual field is measured by flashing lights with different levels of intensity at your side vision to measure whether you have any blind spots in your side vision.
- We will review your glaucoma medications.
- We will videotape you putting in your eye drops to assess your eye drop instillation technique. The eye drop bottle will have a sensor that records the bottle movements.
- You will be randomized to either enhanced standard of care education or the SEE Personalized Glaucoma Counseling Program.
- You will be given a medication bottle to keep your eye drops in that tracks your medication use.

Randomization: This means that the education type you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare the two types of education. If you decide to be in the study, you need to be comfortable not choosing which education group you will be in.

After the initial testing, you will be randomized to either enhanced standard of care or personalized glaucoma coaching through the SEE Program. If you are randomized to the "Enhanced standard care arm," you will be offered a free personalized glaucoma coaching session at the end of your participation in the study if you would like.

- **Enhanced Standard of Care**: You will receive glaucoma education by mail every 2 months for a total of 3 mailings during the 6-month study period. These mailings contain glaucoma education from leading experts including the American Academy of Ophthalmology, the National Eye Institute and the Glaucoma Research Foundation.
- **The SEE Program:** You will meet with a glaucoma coach three times in-person to go over a personalized education plan. At these visits we will check your eye pressure. The coach will call you between your visits to check in to see how you are doing with using your glaucoma medications. You will have the option to have alarms and alerts sent to you if you would like a reminder to take your glaucoma medications.

Follow-up: At the end of the 6-month trial period you will meet with the research staff for a final study visit. This visit will last approximately 60-90 minutes depending upon randomization placement. Research staff will check your eye pressure, video record eye drop installation with the eye drop bottle sensor measuring bottle movement and you will be asked to complete surveys and a program evaluation. We will ask you to turn in your electronic medication monitors. For participants randomized to the SEE Program arm, we will interview you to find out what you liked and didn't like about the program and how the program can be improved. This interview will take about 20 minutes. Participants in the enhanced standard care group will have the opportunity to schedule a free coaching session after completing all follow-up assessments. For all study participants, we will continue to review your medical records to monitor your glaucoma and your glaucoma refill information at your pharmacy for 12 additional months.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled in-person and phone appointments, and report any adverse reactions you may have.

See Part 2 *Site Information* for details about any special procedures at your site.

4.2 How much time of my time will be needed to take part in this study?

Baseline visit: All participants will spend approximately 60 – 90 minutes with research staff

- **Enhanced Standard of Care:** No additional time required.

- **SEE Program Coaching (eHealth):** Three in-person coaching visits, where the first visit is 60 minutes and the following two visits are 30 minutes. Four coaching phone call check-in's, each lasting about 10 minutes. This is a total of about 160 minutes of coaching.

6 Month Final Study Visit: All participants will spend approximately 60 - 90 minutes with research staff

4.3 When will my participation in the study be over?

If you are eligible to complete the trial, your participation will be over after 18 months unless you choose to end your participation sooner.

4.4 What will happen with my information and/or biospecimens used in this study?

Your biospecimens and collected information may be shared with the Sponsor listed above.

With appropriate permissions, your information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information will be stripped of identifiers and may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

This study involves education; therefore, there are minimal risks of physical injury.

This study may ask questions that might make you feel uncomfortable. The researchers will try to minimize these risks by letting you know that you are free not to answer the questions.

Eye pressures will be checked using an instrument that has a single-use disposable probe to limit the risk of infection. This instrument does not require corneal anesthesia, reducing the risk of cornea scratches and reactions to anesthetic drops.

When your intraocular pressure is checked, if it is more than 4mm Hg above your goal pressure set by your physician or over 21 mmHg if there is no set target pressure recorded, you will be taken to the glaucoma clinic for further evaluation and we will contact your ophthalmologist to let them know and determine appropriate follow up. All of your intraocular pressure information will be sent to your ophthalmologist through the electronic health record. If your intraocular pressure is over your target eye pressure at all, your ophthalmologist will receive an email notification as well as a notification through the electronic health record to determine appropriate follow up.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in the Part 2 *Site Information* section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

By participating in this study, you will learn more about your glaucoma and how to best manage it. You may develop new strategies that help you better manage your glaucoma. Your participation will also help create better educational strategies for glaucoma patients in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Taking part in this research study is voluntary and is not a treatment for your eye disease. You may refuse to participate for any reason without risking your future care at this hospital or your relationship with your doctor.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record.

If you decide to leave the study before it is finished, please tell one of the study team persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, if you leave the study before it is finished it will not affect your care with the study doctor(s) or with the Kellogg Eye Center at the University of Michigan or Henry Ford Health System.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Monitoring for side effects or other problems

- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Part 2 *Site Information* or call your health plan's medical reviewer.

See Part 2 *Site Information* for additional information on this topic.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

See Part 2 *Site Information.*

8.3 Who could profit or financially benefit from the study results?

It is unlikely that anyone on the study team will benefit from the results of this project.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have codes entered in it that will allow the information to be linked to you. We shall keep your research record confidential and limit access to only members of the study team. We shall not allow anyone to see your record, other than those who have a right. You will not be identified in any reports on this study. All information obtained in the study will remain confidential when information is published or publicly presented.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not 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 Certificate 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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the sponsor which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING