Reminder-Cue Scanning Training for People with Homonymous Visual Field Loss

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Mass General Brigham

Supplement 1: Protocol

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Alex Bowers
Project Title:	Reminder-cue scanning training for people with homonymous visual field loss
Version Date:	9/3/2025
Version Name/Number:	v2.1

1. Background and Significance

Homonymous visual field loss (HVFL) affects the same side (left or right) of the visual field in each eye. HVFL results from post-chiasmal damage to the visual pathways and is contralateral to the side of the brain injury. The most common cause is stroke followed by traumatic brain injury, tumors, and brain surgery. In the United States, people with homonymous hemianopia (the loss of one half of the visual field) are permitted to drive in states where they meet the visual requirements for either a regular or a restricted license. For instance, they can drive in New Hampshire, Colorado and California where there are no minimum field requirements. People with homonymous quadrantanopia (the loss of one quarter of the visual field) are permitted to drive in most states because their field loss only affects one quadrant rather than a complete hemifield (as in hemianopia).

Drivers with HVFL could compensate for their vision loss by scanning toward the blind side of the visual field using eye and head movements. However, prior research[1-5] suggests that drivers with HVFL sometimes fail to scan to the blind side when approaching an intersection or do not scan far enough resulting in impaired responses to hazards. A large gaze scan, up to 90°, composed of head as well as eye movements, may be needed to see hazards approaching from the blind side at a four-way intersection. People with HVFL do not have any stimuli from peripheral vision as to when to scan to the blind side (because they do not have any peripheral vision on that side). Therefore, they may be unaware that they have failed to scan to the blind side unless there is some consequence (e.g., a near crash, or another driver honks at them)

In a prior proof-of-concept driving simulator study,[6] we evaluated auditory reminder cues as a method to alert individuals with HVFL when they failed to make a large scan to the blind side on approach to an intersection. We found that the reminder cues promoted a more proactive style of scanning, i.e., participants were more likely to make an early large scan in drives with than without the reminders, and participants who scanned less well showed greater improvement than participants who scanned well without the reminders. Moreover, when participants made an early large blind side scan, response times were significantly faster than when they did not make an early scan. These results

suggest that reminder cues might be a useful tool in training aimed at improving scanning of drivers with HVFL at intersections.

2. Specific Aims and Objectives

Based on the positive findings from our proof-of-concept study,[6] the goal of this pilot clinical trial is to evaluate short-term effects of reminder cue training for drivers with HVFL as the basis for a future controlled clinical trial with long-term follow up. We will test the hypothesis that in the short term (1 to 2 weeks) the training improves scanning on approach to intersections.

3. General Description of Study Design

This is an open-label, single-arm, pilot clinical trial to evaluate the efficacy of reminder cue scanning training for people with HVFL. There will be a driving simulator evaluation before and after training to quantify changes in scanning following training.

4. Subject Selection

Inclusion criteria:

- HVFL (homonymous hemianopia or homonymous quadrantanopia) for at least 3 months to avoid the confound of spontaneous recovery (most likely to occur within 3 months of the onset of the field loss[7]).
- Binocular visual acuity of at least 20/40
- Prior (or current) driving experience
- At least 16 years of age (there will be no upper age limit)
- Able to attend multiple study visits at Schepens
- English speaking (sufficient to participate in study procedures)

Exclusion criteria:

- Physical or general health problems that could impair the ability to operate the controls of the driving simulator.

Recruitment sources and procedures:

A trained member of the study team will handle recruitment. Depending on the recruitment source, the study team member will either contact the potential participant or the potential participant will contact the study team member.

Recruitment sources include:

1. RPDR: Research Patient Data Registry
   We will use the RPDR database to screen subjects who have not opted out of receiving information about suitable studies. We will query the database to include patients with an ICD

code of Homonymous Visual Field loss who are alive and do not have ICD codes of other physical or cognitive disabilities listed, and do not have interpreter services mentioned on the list. We will begin by contacting 100 subjects in chronological order from most recent to older encounter dates. The research assistant or postdoc on the study team will use the RPDR database to query this data. Dr. Alex Bowers will be the workgroup leader and approve these requests to receive mailing information of potential subjects to contact. Personalized letters will either be mailed out to these potential subjects or sent via Patient Gateway. (RPDR recruitment letter attached). Persons responding with interest in learning about the study can contact the research assistant or study coordinator on the phone who will then use the telephone script (attached) to explain the study to the participant. The PI will conduct ongoing monitoring of patient responses to ensure that the selection criteria are identifying the right patients and will submit complaints about this method of recruitment to the IRB as an "other" event.

2. MGB Rally
   The project will be advertised on the Rally online platform of Mass General Brigham where the study information will be provided, and anyone can show interest in participation. The potential subjects will be contacted using the telephone script, and/or email attached (depending on the preference they indicate when responding on the Rally website). The preview of the Rally advertisement will be submitted after the protocol is assigned a number.

3. Recruitment from clinics at MEE
   Participants will be recruited from neuro-ophthalmology clinics and the vision rehabilitation clinic at MEE. We will send practitioners a letter requesting their help with recruitment along with a recruitment pack. The pack includes a flyer, an information sheet about the study (for the practitioner to give to patients who might be interested), and a permission-to-be-contacted form. Potential participants can express their interest in one of three ways: 1) By contacting the study coordinator directly using the contact information on the sheet, 2) By indicating their interest via a QR code which links to a REDCap survey where they can enter their basic eligibility information (such as whether they are licensed to drive and whether they have normal vision) and contact information (see uploaded preview of REDCap questionnaire), or 3) By completing the permission-to-be-contacted form, which will be returned to Schepens by the healthcare provider. Potential participants will be contacted using the telephone script and/or email, based on their preference indicated in the REDCap survey or the permission-to-be-contacted form.

4. Recruitment from other clinics in the Greater Boston area
   We will also recruit participants from other ophthalmology and optometry clinics in the Greater Boston area. The procedures will be the same as for recruitment from clinics at MEE.

How recruitment goals match the prevalence rates of the condition/disease being studied and the populations most impacted by the condition/disease being studied?

HVFL affects both genders and members of all racial and ethnic groups. Therefore, during this study, no individuals will be excluded based on race, ethnicity or gender, and every attempt will be made to ensure that minorities and women meeting the eligibility criteria are recruited for participation. It is expected that approximately equal numbers of males and females will be recruited. There are some racial/ethnic group differences in the prevalence of certain diseases (e.g., stroke) that cause HVFL and we expect that this will be reflected in the sample populations that we recruit.

Methods to enhance enrollment of diverse individuals and under-represented populations
We are not proposing any specific outreach programs for recruiting specific gender, racial and ethnic groups, as all eligible participants will be recruited regardless of gender, race and ethnicity.

5. Subject Enrollment

Pre-screening
During the telephone call when potential participants are informed about the study they will be asked if they have homonymous visual field loss (hemianopia or quadrantanopia) and whether they have driving experience (prior or current) (see telephone recruitment script). If they respond no to one or both questions, they will be told that they do not meet the criteria for the study.

Consent process:
Informed consent will be obtained at the start of the first visit. Consent procedures will be conducted in a quiet, private area at the study site by a trained member of the study team. At the start of the first visit, the purpose, risks, and procedures of the study will be explained. Subjects will be given ample opportunity to discuss all aspects of the study and ask questions before signing the form. The PI, Dr. Bowers, will be available to answer questions. If potential participants are unsure about whether they want to participate, they will be able to discuss the study with other people such as family, caregivers, or friends before deciding. They are not obligated to sign the form on the same day, and may take time to decide before signing. Participants will be told that they are under no obligation to do the study and that they can withdraw from the study at any time without consequence. If participants so request, consent forms will be read aloud to them. Participants will be provided with a copy of the consent form.

The process for obtaining consent from non-English speakers if applicable
N/A - Participants will need to speak sufficient English to be able to participate in study procedures. We do not have funds for interpreter services for this project; non-English speakers will not be recruited.

The process to determine capacity to consent and use surrogate decision makers if applicable
N/A – All participants will be capable of providing voluntary informed consent

Procedures to minimize undue influence to enroll investigators' own patients
N/A

Post-consent intervention assignment and randomization method
N/A

6. Study Procedures

Typically, the study will involve 7 visits (Table 1) over a period of about 10 weeks. Each visit will be about 2 hours.

<u>Visit 1: Screening and pre-training driving performance</u>

At Visit 1, subjects will undergo vision screening to determine whether they meet the study criteria. Vision measures will include visual acuity (computerized chart) and visual field extent (Goldmann perimeter). In addition, contrast sensitivity may be measured (computerized chart). Participants will also be administered questions to document demographics, relevant ocular and driving history. Participants who meet the eligibility criteria will then complete a pre-training evaluation of driving performance in the driving simulator (see below). Normally the pre-training driving evaluation will be conducted at Visit 1, but, if necessary, a separate visit will be arranged (e.g., if the participant is fatigued).

Neglect status will be evaluated using clinical tests of neglect such as the Bells test[8] and the Schenkenberg Line Bisection test[9]. Both are pencil-and-paper tests: in the Bells Test, participants circle all the bells on the sheet, while in the Line Bisection Test, they mark the center of each line on the sheet. Cognitive status will be evaluated using the Montreal Cognitive Assessment Test (MoCA).[10]

Visits 2 to 4: Scanning training in the driving simulator

At visits 2 to 4, subjects will receive reminder cue scanning training in the driving simulator. These visits will be scheduled within about a 3-week period (ideally one training visit per week). During training, participants will drive along pre-determined routes in the simulator while their head movements are tracked in real time using the remote camera-based tracking system in the simulator. They will receive a scanning reminder cue whenever they fail to make a large scan to the blind side before entering an intersection. The reminder cue will be in the form of an audio cue (a short “beep” from a loudspeaker on the blind side, as used in the preliminary study) or a tactile cue (e.g., vibrations from the car seat on which the subject is sitting).

Visit 5: Post-training driving performance

At visit 5, participants will complete a post-training evaluation of driving performance in the driving simulator within 2 weeks of finishing the training.

Visit 6: One-month post-training driving performance

To evaluate the short-term effects of the training, at visit 6, participants will complete a post-training evaluation of driving performance in the driving simulator approximately one month after Visit 5.

Visit 7: One-year post-training driving performance

About a year after Visit 6, they will return for a long-term post-training evaluation of driving performance in the driving simulator.

Table 1: Schedule of visits and assessments

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
Informed Consent	X						
Visual acuity	X						
Visual fields	X						
Contrast sensitivity	X						
Neglect tests	X						
Cognitive status test	X						
Ocular, driving and other relevant history	X						
Driving performance evaluation	X				X	X	X
Reminder cue training		X	X	X			

Driving simulator

The simulator (at Schepens Eye Research Institute) comprises multiple screens, an adjustable driver's seat, steering wheel, accelerator, and brake pedals. Participants will drive along predetermined routes in the virtual world guided by audio cues simulating GPS navigation. There will be other traffic on the road and the routes will include a variety of maneuvers in a city environment. Hazards (such as pedestrians and other vehicles) will be programmed to appear in various situations in some of the drives. Participants will be instructed to obey all normal rules of the road, avoiding collisions, and maintaining a speed near the posted speed limit.

After acclimatization and practice drives in the driving simulator, each participant will complete evaluation drives (about 10 minutes each) at Visits 1 and 5- 7 without scanning reminder cues and training drives (about 6 minutes each) with reminder cues at Visits 2-4. Head and eye movements of the driver will be recorded using a remote camera-based tracker mounted in the simulator. In addition, a video camera placed behind the participant will be used to record the screens of the driving simulator to facilitate interpretation of driving behavior data automatically recorded by the simulator. Rest breaks will be scheduled into testing sessions and subjects will be able to take a break or stop at any time, without consequence.

Plans for return of research results

There are no plans to return research results to subjects at the end of the study. If subjects indicate an interest in the outcome of the study, a note-to-file will be made, and the PI may share the final published manuscript with these study participants.

Primary and secondary outcomes

- **Primary outcome measure:** Our primary outcome measure will be the proportion of intersections at which participants make an early large scan to the blind side (side of the field loss) and the proportion of detected hazards approaching from the blind side, pre- versus post-training.
- **Secondary outcome measures:** The secondary outcomes will include additional measures of scanning behaviors (including the number, direction, and magnitudes of scans) and responses to hazards (such as time to fixate the hazard and time to respond).

Study termination criteria

Study participation will be terminated if:

- The subject no longer meets the inclusion criteria
- The subject experiences a serious adverse event

Remuneration Subjects will receive $50 per study visit for study participation and travel expenses will be reimbursed to a maximum of $50.

Masking

This is an open-label study so there will be no masking

7. Risks and Discomforts

All procedures in this study are minimal risk. The risks and discomforts described below are all expected.

Vision Tests

There are no expected risks or discomforts associated with the brief vision tests in this study. These tests are non-invasive and non-contact, requiring only that the subject read aloud what they view on a computer screen or indicate when they see a target.

Driving Simulator

During testing using the driving simulator, there is little risk to the patient's health and safety, apart from the possibility that they experience “simulator sickness.” Simulator sickness is similar to motion sickness and is felt by some people when moving in a simulated environment. The effects can range from slight to severe; most individuals will feel little to no effect. Typically, about 25% of participants experience mild simulator discomfort.

In setting up the simulator environment we have made every effort to reduce the likelihood of simulator sickness. The room is air conditioned (reasonably cool climates have also been shown to be helpful in minimizing the likelihood of simulator sickness). There will also be cool water and crackers on hand. Subjects will be introduced to the simulator environment through a graduated training drive that introduces the subject to the simulator environment in such a way as to minimize the likelihood of simulator sickness. During acclimatization and practice drives, the subject will be instructed to handle turns slowly and not overcorrect steering maneuvers (which can contribute to feelings of simulator sickness). There will be programmed breaks in testing sessions, which will help to reduce the risk of simulator sickness, and subjects will be able to take a break or stop at any time without consequence. In addition, the researcher will ask the subject for their physical comfort after each simulated drive and will offer a break or will terminate the session if necessary.

If any participant experiences simulator discomfort to an extent that the driving simulator session has to be terminated, an expected adverse event form will be completed.

Videos recorded during the driving sessions will be taken from behind the driver's seat so the participant's face will not appear in the recordings.

Confidentiality

Procedures to minimize risks to confidentiality include recording demographic and contact information on a separate form from the rest of the experimental data, storing in locked file cabinets all forms or records with information about a subject that would allow identification, and the use of unique subject identifier codes on all experimental research data forms and electronic data files. Any electronic data files that would allow subject identification are password protected on a secure server.

8. Benefits

Potential Benefits to Participants: Subjects' scanning behaviors may improve following the training.

Potential Benefits to Society: The knowledge gained may lead to the development of improved rehabilitation training for drivers with HVFL, which may improve driving safety.

9. Statistical Analysis

This is an open-label clinical trial to provide data for a future controlled randomized clinical trial. The target sample size to complete the study is 16 participants, based on prior[11] and pilot[12] data showing large cue-related improvements in blind-side scanning (Cohen's d ≈ 0.8), including metrics analogous to the primary outcome for this clinical trial, providing ~80% power for within-subject comparisons (paired t-test, alpha = 0.05). The primary analysis will be a within-subjects comparison of (1) the proportion of intersections with an early large blind-side scan and (2) the proportion of detected hazards approaching form the blind side, pre- versus post-training. Secondary analyses will also be within-subjects comparisons of other scanning behaviors (including the number, direction, and magnitudes of scans) and responses to hazards (such as time to respond to the hazard) pre- and post-training. Analyses will use mixed-effects models (GLMMs for binary, LMMs for continuous) with session as a fixed effect and participant/intersection as random intercepts, assuming model assumptions are met.

10. Monitoring and Quality Assurance

Adverse event reporting

Adverse events will be reported immediately to the PI to review. Expected adverse events will be logged and reported annually at the time of the continuing renewal. Any unexpected or serious adverse events will be reported to the IRB immediately.

Planned safety monitoring

This is a minimal risk, single-site, pilot clinical trial. A data safety and monitoring board is not required. The PI will be responsible for safety monitoring, which will be performed as part of the outcomes monitoring.

Outcomes monitoring

Approximately once a quarter, data summaries will be reviewed by an internal committee comprising the PI and members of the research team at Schepens to monitor data quality, primary outcomes and study progress. Data summaries will be produced by the research assistant (including data on topics such as subject enrollment, withdrawals, primary outcome measures, and any safety issues).

Study stopping rules

There are no study stopping rules (other than the criteria for terminating a subject from the study, detailed in the section on study termination criteria above)

Internal monitoring of source data

The PI has overall responsible for monitoring the integrity of the data. The research assistant will be responsible for ensuring accuracy and completeness of data records and informed consents. Research staff will enter data into study spreadsheets in a timely fashion and all data will be checked by another researcher to ensure integrity. Summaries of data will be reviewed by the study team to further ensure integrity.

Independent monitoring of source data

The proposed research is no more than minimal risk. Independent monitoring of the source data is not required.

11. Select the Privacy and Confidentiality measures that apply to this research:

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

12. References

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Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Reminder-cue scanning training for people with homonymous visual field loss

Principal Investigator: Alex Bowers PhD MCOptom

Site Principal Investigator:

Description of Subject Population: Individuals with homonymous visual field loss

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part.

Throughout the consent form, "you" always refers to the person who takes part in the study.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you have homonymous visual field loss (such as hemianopia or quadrantanopia) and have driving experience. We are doing the research to find out whether training with scanning reminder cues is helpful for people with visual field loss when driving. If you agree, you will have your vision measured and will drive in a driving simulator and receive scanning training in

a driving simulator. You will be in the study for about 10 weeks with an additional follow up visit after 12 months, if you decide to stay for the whole study.

The main risk of being in the study is the possibility of feeling some discomfort when driving in the simulator. Many individuals will feel no effects at all. If felt, these effects last only for a short time, about 10-15 minutes after leaving the simulator.

You might benefit from being in the study because there might be some improvement in your ability to compensate for your visual field loss by scanning.

You will be paid $350 for taking part in this research study. You will find more information about the payment amount for each study visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Alex Bowers is the person in charge of this research study. You can call her at 617-912-2512 at any time during office hours (M-F, 9am-5pm).

If you have questions about the scheduling of appointments or study visits, call Patrick Baker at 617-912-2512.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

Homonymous visual field loss is the loss of vision on the same side in both eyes. The most common types are hemianopia (the loss of one half of the field of vision) and quadrantanopia (the loss of one quarter of the field of vision). People with hemianopia or quadrantanopia may have difficulty in seeing objects on the side of the field loss. They may be able to compensate for the loss of vision by scanning (looking) toward the side of the field loss, but sometimes they might not scan sufficiently well resulting in delayed responses to hazards when driving. The purpose of this research study is to evaluate a new approach to training people with field loss to scan when driving.

Who will take part in this research?

We are asking you to take part in this research study because you have homonymous visual field loss (hemianopia or quadrantanopia) and driving experience.

Approximately 30 participants will take part in this research study.

The National Eye Institute of the National Institutes of Health is paying for this research study to be done.

What will happen in this research study?

Typically, the study will involve 6 visits over a period of about 10 weeks with an additional follow up visit after 12 months (total 7 visits over about 15 months). Each visit will be about 2 hours.

Visit 1: Screening and pre-training driving performance
We may do some or all the following screening tests:

- Ask questions about your ocular history and your driving history
- Test your vision on an eye chart
- Measure your field of vision

If you meet the eligibility criteria, we will invite you to participate in the pre-training driving simulator session. Normally this will be done at Visit 1. However, a separate visit can be arranged (e.g., if you are fatigued). The pre-training driving session includes:

- Practice drives to get accustomed to the driving simulator (described below)
- Study drives for data collection (eye and head movements, and driving behaviors)

In addition, we may ask you to complete:

- Pen-and-paper tests for hemi-spatial neglect
- A test to evaluate memory and thinking

Visits 2 to 4: Scanning training in the driving simulator

At Visits 2, 3 and 4, you will complete training in the driving simulator, including:

- Practice drives to get accustomed to the driving simulator
- Training drives with scanning reminders (described below)

Visit 5: Post-training driving performance

The post-training driving session includes:

- Practice drives to get accustomed to the driving simulator
- Study drives for data collection (eye and head movements, and driving behaviors)
- Your feedback about the training

Visits 6 and 7: One-month and 12-month post-training driving performance

About a month later (Visit 6) and again about a year later (Visit 7), you will return for follow-up driving sessions, which include:

- Practice drives to get accustomed to the driving simulator
- Study drives for data collection (eye and head movements, and driving behaviors)
- Your feedback about the training

Driving simulator

The simulator consists of multiple screens on which a virtual road and virtual traffic are displayed. It has a car seat with a setup like a typical car cabin, with all the usual controls, such as a steering wheel, accelerator and brake pedals. You will be able to take some practice drives in the simulator to get used to the controls and the simulated driving environment. During the study drives there may be some potential hazards such as pedestrians or other vehicles. You should follow all normal driving rules and try to avoid collisions.

The driving simulator task has been designed to be somewhat difficult; you should expect to make some mistakes. You should not feel badly about this. The driving simulator tests differ

from real, on-road driving in an important way: none of the objects that you might accidentally hit while driving in the simulator are real – they are only pictures.

Recording eye movements
While driving in the simulator, your head and eye movements will be recorded with a video system that uses small cameras mounted in the driving simulator. The video images will not be stored; only numerical data of your head and eye position will be recorded and stored securely in electronic format.

Training with scanning reminders
During training drives you will receive reminders when you don't scan enough to the side of your field loss. The reminder will either be a sound from a loudspeaker on the side of your field loss or a vibration (from the car seat) to remind you that you need to turn your head and look toward the side of your field loss.

Video recording
We may use a video camera placed behind the driver's seat to record the screens of the driving simulator. This will help us when we interpret the driving behavior data recorded by the simulator. Your face will not be recorded.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study data and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if

you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

There is a risk of "simulator sickness" from using the simulator. Simulator sickness is similar to motion sickness and is felt by some people when operating driving simulators. The effects can range from slight to severe. Many individuals will feel no effects at all. If felt, these effects usually last only for a short time, about 10-15 minutes after leaving the simulator. In some individuals, feelings of simulator sickness may last for several hours. If someone experiences simulator sickness, they usually feel less discomfort each time they use the simulator.

If you feel uncomfortable, you may ask to stop at any time either to take a break or to stop altogether without consequence. There is a quiet area where you may wait for as long as you want, until you feel comfortable enough to either continue with the study or to safely go home. To reduce the likelihood of simulator sickness, the simulator has been equipped with features to reduce feelings of discomfort. The practice drive is set up to ease you into the simulator environment, which should help to avoid simulator sickness. There will also be cold water and crackers on hand to help relieve any discomfort if it occurs.

If videos are recorded while you are driving in the simulator, they will not show your face because the video camera will be positioned behind the driver's seat with the camera focused on the driving simulator screens.

There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits might include some improvement in your ability to compensate for your visual field loss by scanning. The knowledge gained from the study may help in developing training programs or driver assistance systems to help people with visual field loss drive more safely.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid $350 for taking part in this research study. You will receive $50 per visit following each visit. You will be reimbursed for travel expenses for study visits (up to $50 per visit, including validated parking). We will reimburse you at the end of each study visit.

We may be using an approved, outside vendor (Advarra) to make these payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. If you are paid by this system, you will be given a Participant Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each study visit. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store. We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital. If you provide a receipt for something like travel expenses and we can cover that, that is not considered taxable income. Reimbursement of travel expenses will not be made using the Participant Payments card.

What will you have to pay for if you take part in this research study?

There are no costs to you for participating in this study. Study funds will pay for all study related procedures.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study

- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Subject Signature Date Time (optional)

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her identifiable information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Signature of Parent(s)/Guardian for Child Date Time (optional)

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Child:

I agree to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Signature of Child, Ages 14-17 Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____
Print Name

_____ _____ _____
Signature of Study Doctor or Person Obtaining Consent Date Time (optional)

Consent Form Version: July 28, 2025