Informed Consent Document
To Be Part of A Research Study

TITLE OF RESEARCH: New Methods to Quantify and Train Eye Movement Strategies in Macular Degeneration

UAB IRB PROTOCOL#: IRB - **300008064**

PRINCIPAL INVESTIGATOR: Dr. Kristina Visscher

SPONSOR: National Institute of Health: National Eye Institute

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of this project is to understand how people learn to use peripheral vision following loss of central vision.
Duration & Visits	Participating in this study will require about 9 visits total. The first visit is for retinal testing, like at your optometrist or ophthalmologist's office. This should take around 1.5 hours. Three visits are for vision testing, one at the beginning, one after training, and one long term follow-up after two months. These visits should take around

	1.5 hours, and not more than 2 hours. The remaining five training visits should be about 1.5 - 2 hours each.
Overview of Procedures	This research study will test how your brain learns to see things in peripheral vision. The first visit will involve "retinal testing" to take pictures of your retina and confirm that you have central vision loss. Training visits involve playing a simple video game in our laboratory, while we record your responses. Testing visits involve computerized tests of vision and cognition.
Risks	**Psychological stress during training, cognitive tests or questionnaires.** There is a risk the phone interview questions may make you uncomfortable. **Retinal Testing**: The risks and discomforts associated with the retinal testing are the same as those associated with having a standard eye examination. **Training:** There is a risk the training sessions may be tiring, or make you uncomfortable.
Benefits	You will not benefit directly from taking part in this study. However, this study may help us better understand brain function after central vision loss and visual training and could lead to improved treatments after vision loss.
Alternatives	If you do not want to take part in the study, you have the alternative of not participating.

	This will not prejudice your relationship with anyone at UAB.

Purpose of the Research Study

We are asking you to take part in this research study that will test how you learn to use peripheral vision. This study will enroll about 100 people who have central vision loss.

Persons with central vision loss are sometimes able to use these unaffected parts of their visual field to perform tasks such as reading or recognizing faces that normally would use central vision. Training people to effectively use their peripheral vision for these tasks is important to improve performance on everyday activities, and can improve quality of life. However, we do not know what the most effective training is. There are multiple factors involved in using peripheral vision, for example, one factor is learning to move ones' eyes differently, while another is learning where the edges of usable vision are. This research is aimed to identify which factors can be improved, and how improvement in those factors relates to everyday tasks. This research is important for developing effective training methods for people with vision loss.

Study Participation & Procedures

If you agree to participate in this study it will require about 9 visits total.

- The first visit will involve a "retinal testing visit" to take pictures of your retina and confirm that you have central vision loss. This is described below under “Retinal testing visit.”

- Five visits are for training. These visits involve playing a simple video game in our laboratory, while we record your responses. These visits should take about 1.5 hours total. These are described below under "Training."
- Three visits are for vision testing, one at the beginning, one after training, and a follow-up training about two months later. These visits should take around 1.5 hours, and not more than 2 hours. These are described below, under "Vision Testing"

To be in this study, you must be between the ages of 18-89 years old. You cannot be in this study if you are not in good health, had a previous serious head injury that could have affected your brain, or have trouble sitting still for long periods.

Retinal testing visit: You will have your retinal health tested using measures much like those in your own eye doctor's office.

- We will dilate your eyes using drops identical or very similar to those used during a comprehensive eye exam that would be carried out by your eye doctor.
- You will be shown some pictures in different locations, and you should indicate whether or not you can see them, and we will make several pictures of the back of your eye.
- You will also be asked some questions to test your general health and vision. You will be shown a type of video game and will practice this game.

Training. During training, you will be shown abstract images on a computer screen. The images you will see will include abstract images like black and white stripes that may appear in the center of the

screen, or elsewhere on the screen. You will respond to those images by pressing a button indicating something about the images, for example, whether a set of lines is pointing to the left or to the right. During training we will record where your eyes are looking on the computer screen. You will perform this task for about 90 minutes with regular breaks, each time you come to the lab for training. You will come to lab for training a total of 5 times, at times that work with your schedule. You will perform the same task each time, but as you get better, the task will get slightly harder, so that it feels similarly difficult to you on every session. There are 2 slightly different versions of the training, both of which are designed to improve your ability to use your peripheral vision. You will be assigned to get just one of them. The training versions differ only on the specifics of exactly what type of abstract images are on the screen and what part of the screen is visible to you. The amount of time you will spend training, and the computer and room you will be in are identical regardless of the training.

Vision Testing: You will complete additional visual tests to assess your visual acuity and peripheral vision that will involve looking at different charts. Some of the tests are computerized vision tests, which involve pressing buttons in response to different images on a computer screen and also involve recording your eye movements as you perform the task.

Phone Interviews: You will be contacted at home a few days before your first appointment to answer your questions about procedures. We will call you at a time that is convenient for you.

Eye Exams during Retinal Testing visit: If any incidental findings are discovered during the eye exams, you will be notified in order that you can obtain appropriate follow-up care. You will be responsible for following up on the information we provide you about any abnormal finding and for any associated costs. Note that this review of your general health and vision should not be considered a medical exam or a medical procedure, and is not a substitute for any medical care.

Risks and Discomforts

Psychological stress during training, cognitive tests or questionnaires: You will be asked to complete vision, thinking and memory tasks that might be difficult. You might feel frustrated or uncomfortable during these tasks. Understand that the tests are designed to challenge people.

You will also be asked to complete questionnaires that ask questions about your feelings, behaviors, and medical history. Some of the questions may deal with issues that make you feel uncomfortable or cause you to feel stress. You do not have to answer a question that makes you feel uncomfortable.

Study staff will be available to answer any questions.

Phone Interviews: There is a risk the questions may make you uncomfortable. If this occurs, you can refuse to answer the question.

Retinal Testing visit: The risks and discomforts associated with the retinal testing are the same as those associated with having a standard eye examination. You may be surprised at the very brief

light flash during the vision testing. However, the staff member administering the test will tell you when the test is about to begin. The drops used to dilate your eyes may cause brief minor discomfort in your eyes (for example, burning, tingling, or watering), which typically goes away within 5 to 30 seconds.

Breach of Confidentiality: As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Information for Women of Childbearing Potential or Men Fathering a Child

There are no known risks of performing cognitive and vision tests to pregnant women or to sperm of men capable of fathering a child.

Benefits

You will not benefit directly from taking part in this study. However, this study may help us better understand vision after central vision loss and could lead to improved treatments after vision loss.

Alternatives

You have the alternative of not participating in the study. This will not prejudice your relationship with anyone at UAB.

Confidentiality and Authorization to Use and Disclose Information for Research Purpose

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor

must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Who may use and give out this information?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or

elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, Eye Foundation Hospital, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The study staff will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

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 NIH 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 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 www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study principal investigator. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others, including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. If you choose to leave early, you will still be paid for the portion of the study you have completed.

You may be removed from the study without your consent if the sponsor ends the study, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There are no costs to you for participating in this study.

Payment for Participation in Research

If you are not considered eligible for the study after the first day of screening, you will be paid $25. You will be paid at a rate of $10 per hour for the study. Training sessions are computerized and therefore limited in time by the computer. If you do not finish the entire study, you will be paid hourly at a rate of $10 per hour of training and testing that you do complete. If you complete the entire study, (1 retinal testing visit, 3 behavioral testing sessions plus 5 training sessions) you will receive $250. Payments will be made within approximately 14 days of the last day of study participation. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

New Findings

Any significant new findings that develop during the course of the research which may relate to your willingness to continue participation will be provided by Dr. Visscher.

Optional

Data Sharing

Letting us use and share your data is voluntary. However, you must be willing to share your data in this way in order to participate in this study. If you are not willing, you cannot participate in this study.

The data and from this study might be used for other, future research projects. Future projects might be unrelated to the goals of the current study. We will give access to some of the data, to the general public via the Internet and a fully open database. The data we will share publicly are limited to your responses to questions and computer games that will keep you anonymous and not identify who you are. Additionally, we will make data available to other investigators through a controlled access database. To minimize risks to your privacy, a committee of experts will carefully review every data request from other scientists before allowing them to use this database to which we control access, in order to make sure they can also protect your personal information. These other investigators may be at UAB or at other research centers (academic or commercial) around the world.

If you change your mind and withdraw your consent to participate in this study (you can call Dr. Kristina Visscher at 205-934-0267 to do this), we will not collect any additional data about you. We will delete your data if you withdraw before it was deposited in the database. However, any data and research

results already shared with other investigators or the general public cannot be destroyed, withdrawn or recalled.

It is possible that some of the research conducted using your information could lead to the development of new methods for studying vision, new diagnostic tests, new drugs or other commercial products. Should this occur, you will not have any part of the profits generated from such products and you will not have any ownership rights in the products.

To the best of our knowledge, the data we release to other investigators or the general public will not contain information that can directly identify you. The data will be labeled with a code that only Dr. Visscher can link back to you. In addition, the data made available to members of the general public will not include data that we think might help people who know you guess which data are yours, such as your facial features or the date that you participated. However, by using additional data linked to your name one could potentially link your information in our database back to you. In addition, a security breach (break in or cyber-attack) might lead to someone being able to link you to your data. This risk is very low because your data are stored in a secure database, and the information about your identity is stored separately from the data themselves, linked only through a code.

We will keep the private portion (name, contact information etc.) of your data in a secure location for 1 year. After one year we will destroy this information.

By initialing below, you agree to provide your data for future research. You agree that these may be shared with other authorized investigators at other institutions from around the world. The details, results, and meaning of these studies are unknown.

Initial your choice below:

___ I consent to my data being added to a database for future studies.

___ I do not consent to my data being added added to a database for future studies.

Future Contact

We may want to contact you in the future. You can decide now whether or not you want to be contacted. You can also change your mind later.

We may provide your contact information to other researchers for recruitment into their studies. They will contact you and tell you about their study so you can decide if you would like to receive more information. There would be a new consent process for that study. You can decide then if you would like to take part in that study or not. You can decide now whether or not you want to be contacted. You can also change your mind later.

Initial your choice below:

___ I agree to be contacted about future research.

___ I do not agree to be contacted about future research.

If at any time you decide you no longer want to be contacted about this study or contacted about future studies, you can call Dr. Kristina Visscher at 205-934-0267.

Questions

If you have any questions about the research Dr. Kristina Visscher will be glad to answer them or get answers to them. Dr. Visscher's phone number is 205-934-0267.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of person obtaining consent Date