Informed Consent for NCT05265624

The Moran AMD Genetic Testing Assessment Study (MAGENTA)

The following pages contain the most up to date version of the informed consent that was approved by the IRB for this study. It was approved with our 2022 annual renewal. Consent approval date: 08 February 2023.

Consent and Authorization Document

STUDY TITLE: **The Moran AMD Genetic Testing Assessment Study: MAGENTA**

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STUDY SUMMARY

You are being asked to join a research study. The research is for people who want to learn more about their risk for developing age-related macular degeneration (AMD). Before you consider the research, you should be aware of the following information:

- Research is voluntary. You do not have to be in this study.
- You may qualify for this study if you are between 18 and 64 years old and you have never received genetic testing results for AMD risk.
- You can get standard care for your eye care even if you decide not to be in this study.
- The goal of this research is to study whether knowing a person's risk for AMD motivates them to make sustained lifestyle changes that can decrease their risk of developing AMD later in life.
- This study uses investigational cameras to take pictures of the inside of the eye. The cameras are not approved by the U.S. Food and Drug Administration. This study uses research labs to analyze blood samples. Results from the research labs will not be used in your clinical care.
- This study will last for one year. Everyone in the study will answer questionnaires, have pictures of the inside of their eyes taken, and have blood taken during the study. You will either be assigned to a group that gets their genetic results at the beginning of the study or another group that gets their genetic results at the end of the study. The group you are assigned to will be decided by chance, like flipping a coin. The study procedures are described in more detail later in this document.
- There are some risks and discomforts from the study procedures. These are described in detail later in this document. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this study.

If you think you want to be in this study please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study. If you decide to take part in the study, you will be asked to sign this form.

BACKGROUND

Age-related macular degeneration, or AMD, is a common eye condition among older people. AMD is a leading cause of central vision loss in people over 50 in the developed world. It gradually destroys the macula, the part of the eye that provides sharp, central vision needed for seeing objects clearly. Approximately 10-15% of people who develop early AMD progress to end stage disease, either geography atrophy (GA or "dry" AMD) or choroidal neovascularization (CNV or "wet" AMD). Choroidal neovascularization (also referred to as advanced AMD) happens when new blood vessels under the macula leak blood and fluid. In CNV, damage to the macula can occur rapidly. CNV accounts for 90% of vision loss associated with AMD. Patients who have vision loss experience changes to independence as well as their ability to care of themselves and other family members.

Genetic testing is available for AMD through research laboratories. It is not currently available through CLIA-certified laboratories.

We know that certain changes in DNA lead to increased risk to develop AMD. During routine clinical care of patients with AMD many family members who do not have any symptoms of AMD have been interested in understanding their personal risk of developing AMD. Previously, family members could receive genetic counseling that could identify their population risk based on the relation of the affected family member, but further information could not be provided about how their risk may differ from their siblings based on inheritance. Also, many patients without a family history of AMD have also sought more information about risk due to heightened awareness in the general community.

Although the American Academy of Ophthalmology (AAO) does not recommend routine genetic testing for AMD risk, patients can still modify lifestyle behaviors to help reduce their risk of developing AMD as well as progressing to choroidal neovascularization. Some of these modifications include smoking cessation, weight loss, and incorporating dark leafy vegetables and cold-water fish into their diet.

PURPOSE OF THE STUDY

The goal of this research is to study whether knowing a person's risk for AMD motivates them to make sustained lifestyle change that can decrease their risk of developing AMD later in life. This is a randomized trial to compare immediate versus deferred information about AMD genetic risk: 75% of subjects will receive their genetic test results at the beginning of the study. 25% of the subjects will have their results disclosed to them one-year later at the end of the study.

STUDY PROCEDURES

If you agree to take part in this study, we will ask you to come to the clinic for a total of six study visits over the course of a year.

Baseline Visit – Month 0

- At the Baseline Visit **we will review the study and this consent form with you** before doing any other study procedures.
- **We will record your height and weight.**
- **We will ask you to complete five surveys** that will take approximately 30 minutes to complete. You may complete them electronically or on paper either at your study visits or in advance of each visit.
    - The Hospital Anxiety and Depression Scale (HADS) includes 14 questions designed to measures levels of anxiety and depression
    - The Impact of Events Scale (IES) includes 15 questions designed to evaluate the impact of a specific event
    - The Tufts LZQ™ Screener includes several questions designed to assess dietary carotenoid intake. Carotenoids give red, yellow and orange color to plants. They are taken up from the diet where they exist in particularly high concentrations in green leafy vegetables and orange-yellow fruits. There is some evidence that these carotenoids protect the colored region of the retina from some types of macular degeneration.
    - AMD knowledge survey
    - Lifestyle Questions

- **We will measure the carotenoid levels in your skin** using two scanners that uses a painless blue light for exposure of the skin and a photodetector for collecting scattered light. We will ask you to hold the palm of your hand or your finger against a small optical module for less than a minute to take a reading. The Veggie Meter is a commercially available device that assesses nutritional status. The Resonance Raman Spectroscopy (RSS) scanner is not FDA approved and is used for research purposes only. The light intensity of the RRS instrument is comparable to a laser pointer and is considered safe as long as it is not pointed into the eye for a prolonged period of time.
- **Macular pigment measurements in the eye and Fluorescence Lifetime Imaging Ophthalmoscopy (FLIO)**
    - We will take pictures of the inside of your eyes with a specialized camera routinely used for standard ophthalmology care. Our camera uses a software program that measures the amount of pigment in the macula. This software program is not yet FDA approved and is used for research purposes only.
    - FLIO imaging is done on a camera similar to the camera used in routine clinical care. FLIO is a new way to image macular pigment and other compounds in the eye. The FLIO system is not yet FDA approved and is used for research purposes only.

- **Color Fundus Photography, Autofluorescence (AF) and optical coherence tomography (OCT)** – We will take these additional photos to make sure you are not already showing signs of AMD or another eye disease that would make you ineligible to take part in the study. These photos will be reviewed after your study visit. If they show you are eligible to continue in the study, we will call you to make an appointment for your next study visit.
- **High-Resolution OCT Imaging** – We will photograph the inside of your eyes using the Heidelberg Spectralis High Resolution OCT. This camera uses a slightly different wavelength laser than the standard clinical OCT camera and is not FDA approved. We are using it for research purposes only.
- **Dilation** – In order for us to obtain images of the inside of your eyes, we will need to dilate your eyes. Your pupils will remain dilated for several hours.
- **We will draw your blood** for genetic testing and to measure carotenoid levels in your blood. The total amount of blood to be drawn is a little more than a tablespoon.
    - Your genetic sample will be analyzed in Dr. Hageman's research lab at the Moran Eye Center and your carotenoid samples will be analyzed in Dr. Bernstein's lab at the Moran Eye Center. Results from these laboratories will not be included in your medical record since these are not CLIA certified labs.
- The Study Coordinator will **review with you AMD risk factors** and strategies to reduce those risks.
- **If you are eligible to continue in the study, we will randomize you to one of two groups**. One group will receive genetic counseling and results from genetic testing at the beginning of the study. The other group will receive genetic counseling, but results from genetic testing will be withheld until the end of the study (12 months after you begin the study). Randomization will be assigned by a computer, not by the study staff. For every participant who is assigned to the deferred disclosure group, three participants will be assigned to the immediate disclosure group.

Disclosure Visit – Month 1

- The genetic counselor will meet with you to tell you which group you have been assigned to, to review with you AMD risk factors and strategies to reduce those risks, and to answer any questions or concerns you have. The genetic counselor will ask you to complete a survey regarding genetic counseling.
- If you are assigned to the immediate disclosure group, the genetic counselor will give you those results and discuss them with you.
- We will tell you at this visit which eye has been assigned as your study eye.
- We will measure your skin carotenoids.
- We will ask you to complete the Nutritional, Lifestyle, HADS and IES surveys.

Month 3 Visit

- We will ask you to complete the Nutritional, Lifestyle, HADS and IES surveys.
- We will measure your skin carotenoids.

Month 6 Visit

- We will ask you to complete the Nutritional, Lifestyle, HADS and IES surveys.
- We will measure your skin carotenoids.
- We will take Macular Pigment and FLIO images of your study eye. We will dilate your study eye for these images.
- We will measure your height and weight
- We will draw your blood to measure the carotenoid levels in your blood.

Month 9 Visit

- We will ask you to complete the Nutritional, Lifestyle, HADS and IES surveys.
- We will measure your skin carotenoids.

Month 12 – Closeout

- We will ask you to complete the Nutritional, Lifestyle, HADS, IES and AMD Risk & Genetic Counseling surveys.
- We will measure your skin carotenoids.
- We will take Macular Pigment and FLIO images of your study eye. We will dilate your study eye for these images.
- We will measure your height and weight
- We will draw your blood to measure the carotenoid levels in your blood.
- The genetic counselor will ask you to complete a survey regarding genetic counseling. If you were assigned to the deferred disclosure group, the genetic counselor will discuss your test results with you and address any questions or concerns you have.

RISKS

There is a risk of loss of confidentiality from medical record review, but procedures are in place to prevent any such loss.

There will be brief discomfort from the needle stick. It is possible that there will be bruising or oozing of blood afterwards. Rarely, there is a risk of infection.

Genetic testing may involve emotional stress and may result in discrimination (insurance or work-related). There is a law in place, the Genetic Information Nondiscrimination Act (GINA) that prevents insurance companies from discriminating based on genetic testing results. This act also prevents employers from discrimination based on genetic testing as well. If you would like more information about GINA it can be provided to you. The testing is performed by a well-qualified research laboratory but it is not a CLIA certified clinical laboratory, so the genetic testing results will be given to you, but they will not be entered into your medical record. Not adding genetic results to your medical record reduces the risk of discrimination.

Throughout this study we will take every reasonable step to protect anonymity. However, there can be no absolute guarantee of confidentiality, and there is a small chance that results may have a negative impact on you or your family. These may include insurability, employability, and/or family relationships.

There are no expected side effects from the light exposure for the skin measurement. It is important not to look at the laser directly for a long period of time.

To complete the eye photos, your eyes will need to be dilated with eye drops. Your vision will be mildly blurred, and your eyes will be more sensitive to light for several hours. Rarely, there can be an allergic reaction to eye drops, corneal scratch from rubbing of eyes, or closed angle glaucoma from dilation drops. We suggest you bring a pair of sunglasses to wear after the visit as these can help with comfort.

If you have high blood pressure, an irregular heartbeat or glaucoma, these conditions may get worse when using the dilating drops. However, this can be managed so please discuss this with the study coordinator.

Light levels projected on the retina in this study for macular pigment measurements and ophthalmic photos are well within established safety limits. You may notice a central dark spot in their vision similar to the afterimage generated by a camera flash. This afterimage will fade away within approximately 5 minutes.

You may experience anxiety or distress upon learning your genetic risk of AMD or your assignment to the deferred disclosure group. A trained genetic counselor is available to address any questions or concerns about your genetic testing results. If you experience significant distress or anxiety, we will refer you to Dr. Lisa Ord for psychological counseling at no cost to you.

BENEFITS
We don't know if being in this study will benefit you directly, but may encourage you to make positive lifestyle changes that could lower your risk of vision loss later in life.

Positive results from this study could lead to wider use of genetic testing that would encourage high-risk individuals to make lifestyle changes that could lower their risk of vision loss later in life. If negative results are obtained, then we will have provided further evidence that the AAO's stance against routine genetic testing for AMD risk in asymptomatic individuals is correct.

ALTERNATIVE PROCEDURES
You may choose not to participate in this study. If you do not want to take part in the study, there are other choices, such as receiving genetic counseling or genetic testing outside this study. You may discuss these options with your doctor.

CONFIDENTIALITY
Results of this study may be published, but your identity will not appear in any such publication.
We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept locked in filing cabinets or on computers protected with passwords. Only those who work with this study or are performing their job duties for the University of Utah will be allowed access to your information.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, please call Dr. Paul Bernstein at (801) 581-4069. Dr. Bernstein can be reached during regular business hours Monday through Friday.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns, which you do not feel you, can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION
It is up to you to decide whether or not to take part in this study. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard of care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

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Institutional Review Board
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Expires 2/7/2024
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If you want to stop being in this study, please let Dr. Bernstein, the principal investigator for this study, know. That way you can find out what should be done about your routine care outside of the study.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged, nor will your insurance company be charged, for any test or visit that is completed solely for the purpose of this study. You will receive a $40.00 gift card for each of the first two study visits and $120 at the final study visit ($30 per visit for the remaining four study visits), up to a maximum of $200.00. You will receive payment for the study visits you complete regardless of whether or not you complete the study.

NUMBER OF PARTICIPANTS

We expect to enroll 80 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, telephone number and e-mail address
- Related medical information about you like family medical history and information from eye examinations
- All other tests and procedures that will be performed in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and University of Utah Health Sciences Center;
  - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
  - The National Institutes of Health (NIH), which is providing the funding for this study;
  - Heidelberg Engineering, Inc. the company that makes the retina cameras and software;
  - The FDA, who is authorized to ensure the integrity of the research.

- If we share your identifying information with groups outside of University of Utah Health they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
- Study data may be made available to other researchers. Your name or other identifying information will not be released.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research. This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____	_____	_____
Participant's Name	Participant's Signature	Date

STATEMENT OF STAFF OBTAINING AUTHORIZATION AND CONSENT

I have carefully explained to the participant the nature and purpose of the above study in language understood by the participant. I provided the participant enough time and an adequate place to read and review this form and discuss the study with study investigators and/or family members. I have answered the participant's questions to their satisfaction. The participant voluntarily agreed to participate in the study and personally signed & dated the consent prior to any study procedures being done. I will provide the participant a signed copy of this form to keep.

_____	_____	_____
Name of Person Obtaining Authorization and Consent	Signature of Person Obtaining Authorization and Consent	Date

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