CONSENT FORM

High Resolution Imaging of the Fovea

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This consent form describes a research study, what you may expect if you decide to take part in it and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have participated in another study in the Principal Investigator's lab.
- The purpose of this study is to capture images of microscopic features of your retina for comparison with the eye-tracking data gathered from a study that you have already done.
- Your participation in this study will last for about 2-4 hours in a single visit.
    - If you choose not to undergo the eye exam today, you can give us permission to contact your eye doctor for your most recent eye exam records. We will ask you to come back for a second test visit after we have received those records.
- Procedures will include an initial eye examination, pupil dilation, and retinal imaging. Some of these procedures may be optional.
- There are risks from participating.
    - The most common risk is loss of privacy.
    - One of the most serious risks is an allergic reaction to the dilation agents. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You will not benefit from being in this study.

Purpose of Study

The purpose of this study is to investigate the anatomy of the fovea and parafovea, which are small parts of your retina that are responsible for sharp central vision. The fovea has a high concentration of closely packed cones and nerve fibers. The images that we gather in this study will be cross-referenced with the eye movement data that we gathered from other studies you already participated in. We hope to better understand the connection that foveal anatomy has with eye movements and attention.

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Description of Study Procedures

If you decide to take part in this study, you will be asked to a standard eye examination, receive eye drops to dilate your pupils, and sit at the adaptive optics scanning laser ophthalmoscope system so that we may take an image of your retina.

1) **Initial eye examination**. This comprehensive exam is similar to what you would normally undergo at an eye doctor's office. It will involve the following steps:

   - A Snellen eye chart (the standard eye chart used at an eye doctor's office)
   - Measurement of refractive errors in your eye, both objectively (using a retinoscope or an autorefractor), and subjectively (using a standard phoropter)
   - Axial length measurements made with an IOL Master
   - External eye exam using a slit lamp
   - Internal eye exam using an ophthalmoscope; your pupil will be dilated for this procedure

   This eye exam is to ensure that your eyes are healthy enough to participate in the rest of the study, and that you have no apparent risk of acute glaucoma. If the exam concludes that you are able to participate in the study, then we will continue with the rest of the study procedures. If not, you will be paid for your participation and dismissed from the study.

   If you have had an eye exam within the past year and would prefer not to do the screening at today's visit, you have the option to provide us with permission to contact your ophthalmologist (eye doctor) to get a copy of your most recent eye exam records. Please see the checkboxes at the end of this document.

2) **Pupil dilation**. The dilating agents are standard drugs commonly used by eye doctors during routine eye exams. They come in the form of eye drops, and either trained study personnel will administer them or you can administer them to yourself. The drops take some time to take effect. Once they have taken effect, we can move on to the final step of the study.

3) **Retinal imaging**. This will involve sitting at the adaptive optics system and viewing a visual target through the system. You will be asked to use an input device such as a keypad or a set of knobs to modify the corrections introduced by the system until the best image is obtained. The machine will take an image of your retina while you are doing this. As part of this, we will also scan your eye for aberrations that may explain quirks in the data that we get.

All study procedures will take place in the Flaum Eye Institute at the University of Rochester Medical Center.

Number of Subjects
Approximately 30 subjects will take part in this study.

Risks of Participation
Risks from this study are no greater than those experienced during routine eye examinations.

Acute glaucoma: A very small percentage of people have eyes that are susceptible to an acute pressure rise (acute glaucoma) when the pupils are dilated with eye drops. In most cases, this susceptibility can be detected by the eye examination that will be given before any drops are used. The drops will not be used if your eyes show signs of susceptibility.

Allergic reaction: There is a small chance that you may have an allergic reaction to topically applied eye drops. Common side effects include: burning or stinging of the eye, headache, browache, light sensitivity, watering of the eyes, conjunctival redness, and blurred vision. If you experience these or any other side effects, please notify the study team immediately. The reaction will clear itself up in one to three days, or it can be treated with an anti-inflammatory medication if needed. If for any reason you do not want the eye drops to be used, you are under no obligation to continue their use and may stop their use at any time.

Discomfort: There is a small chance that you will become uncomfortable from sitting at the scanning machine for a long time. If that happens, you are free to signal to the study team that you need a break or that you wish to stop the study procedures.

Light levels: The retinal imaging procedures carry no additional risk. The study team will carefully monitor the light levels used by the adaptive optics machine to ensure that they stay within safe levels.

Privacy: The study team will make every effort to keep the information collected from you confidential. Please see the section below ("Confidentiality of Records…") for more details.

Benefits of Participation
There is no direct benefit to you for participating in this study. We will explain to you how your screening turned out so that you may discuss the results with your doctor if you wish.

Costs
There will be no cost to you to participate in this study.

Payments
You will be paid $15 per hour for taking part in this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will assign you a random, unique study number, which will be used instead of your name in identifying your data files and in all reports, publications, and references to you. All of the information we collect will be stored in a secure manner and only study team members will have access to it. Results of the research may be presented at meetings or in publications, but your name will not be used. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If this does happen we will take precautions to protect the information you have provided.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institutes of Health

Why will this information be used and/or given to others?
- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information/Samples
Your retinal images might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your images are used or distributed.

Circumstances for Dismissal
You may be withdrawn from the study if you do not keep appointments for study visits or if you cannot complete study activities.

Sponsor Support
The University of Rochester is receiving payment from the National Institutes of Health and the National Science Foundation for conducting this research study.

Return of Research Results
In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Martina Poletti at (617) 358-1385 or Dr. Mina Chung at (585) 273-3937.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

For University of Rochester students: Participating in this study will not affect your class standing or grades at the University of Rochester. You will not be offered or receive any special consideration if you take part in this research.

For University of Rochester employees: Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

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CONSENT TO CONTACT OPHTHALMOLOGIST

May we contact your ophthalmologist (eye doctor) to get a copy of your most recent eye exam records within the last six months?

Yes _____ No _____ N/A _____

Note:

If you answer “Yes”, we will contact you to return for the test session after we have received and reviewed your eye exam records. If those records do not provide adequate information, another eye exam may need to be performed prior to imaging.

If you wish to undergo the eye exam screening today, answer “No”.

If you have not had an eye exam within the past six months, answer “N/A”.

If you do not wish to participate in this study, please inform the researcher.

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date