Eye Movements, Visual Perception and Attention

Informed Consent Form

NCT03884985

Date: 2/27/2025

CONSENT FORM

Eye Movements, Visual Perception and Attention

Principal Investigator: Martina Poletti, Ph.D. **Co-Investigator:** Michele Rucci, Ph.D.

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your educational status and/or employment status will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you are an English speaker who is at least 18 years of age and has passed the vision screening test.

This study is being conducted by Dr. Martina Poletti and Dr. Michele Rucci of the University of Rochester's Center for Visual Science.

Purpose of Study

The purpose of this study is to understand the pattern of eye movements and attentional shifts performed by humans during the analysis of different visual stimuli. More specifically, we are interested in determining whether small involuntary eye movements play a role in how the brain acquires visual information during fixation, and in the allocation of visuospatial attention within the central region of the visual field. We will use eye movement data, an image of your retinal anatomy acquired with an optical coherence tomography (OCT) scan, and, for some experiments, data on brain activity. This correlation of data will help us better understand the neural mechanisms and anatomy underlying the human vision system.

274 Meliora Hall, Box 270270 G-4110 Med. School, Box 319
Rochester, NY 14627-0270
(585) 275-2459
(585) 271-3043 fax

RSRB Approval Date: 2/27/2025
Expiration Date: 2/26/2026

Description of Study Procedures

We have already performed a visual acuity screening, which has determined that your vision is good enough to qualify you for participation in this study. We will perform a second screening at the end of the experimental session. You will be informed of the results of both optometric tests and recommended to consult an ophthalmologist if abnormal fluctuations of visual acuity are observed. If you decide to take part in this study, you will be asked to sign the consent form and provide your date of birth before we do the following study procedures.

Study Visit 1 (Demo Session)

Visit 1 will take about one hour to complete. At this visit, we will:

- Test your visual acuity using a standard Snellen eye chart
- Explain the experimental procedure and the task
- Run a demo of the experiment and of the calibration procedure
- Make a customized bitebar to be used during the experiments in the subsequent study visits
- Repeat the demo of the experiment using the bitebar

Subsequent Study Visits

Study visits following the first visit will take one hour each to complete. During these visits we will ask you to perform the same visual task described in the demo session. Typical tasks involve detection/discrimination of briefly presented visual stimuli.

During each visit you will perform the task multiple times under different conditions; each repetition of the task is called a trial. A typical experimental session of one hour will be divided in batches of trials each lasting no longer than 10 minutes, with breaks in between batches in which you can stretch and walk around if you want to. Before each batch of trials, a short calibration will be performed. In the calibration procedure, you will be asked to fixate on a number of points on the display. Within one session (experiment) there are usually 4 batches of trials. Each session is conducted in separate visits/days, and all of them will take place in the Active Perception Laboratory at the University of Rochester.

Some experiments will also use a non-invasive electroencephalography (EEG) cap. For these experiments, you will be asked to wear a cloth cap fitted with electrodes which will measure the electrical activity on your scalp while you perform the tasks in the experiment. The system uses medical gel to help convey electrical signals to the electrodes. You will be provided with shampoo and a clean towel to wash your hair in one of the lab sinks after the experimental procedures are complete. Set-up and cleanup of the EEG part of the experiment are expected to take up to 30 minutes each; therefore, experimental sessions that involve EEG procedures may take up to 3 hours each.

After you have come in for a few sessions, we will ask you to sit for an OCT scan. We will do this scan as part of one of your normal visits. You will be asked to sit with your head in a chinrest for about 15 minutes while our OCT machine scans your eyes

noninvasively. This scan will give us information about the anatomy of your retina. The data from this scan will help us understand the link between eye movements and retinal anatomy.

Number of Subjects
Approximately 550 subjects will take part in this study.

Duration of the Study
Each experiment session will last at least one hour and you will be asked to participate in multiple sessions over the course of several weeks. Some people will be in as few as 3 sessions while others will be in as many as 30. Most subjects are in an average of 5-10 sessions. The investigator has informed you of the number of sessions that this experiment is expected to include. You may also be asked, via your preferred method of contact, to come back for a follow up experiment. Follow up experiments are completely voluntary and may span the duration of time as stated above or it can be shorter.

Risks of Participation
The experiments present minimal risk. Computer monitors and virtual reality displays are unable to display images at potentially dangerous intensities, and the contrast and brightness of the display may be adjusted to the level that you find most comfortable. In the unlikely event that the image is too bright or you experience any discomfort in looking at the display, simply look somewhere else and inform the investigator. The eye-tracker is non-invasive and there will be no physical attachment between you and the device. The EEG gel might cause some slight discomfort if left on for long periods of time; therefore, we advise you to wash it out of your hair at the conclusion of the session. If at any moment you do not feel comfortable, simply lift your head from the chin rest or remove the virtual reality display. You can and should stop/terminate the experiment at any time if you do not feel comfortable. The apparatus is lightweight and there is no significant potential risk to your body, even should you accidentally bump into the eye-tracker. The OCT machine carries no additional risk. You will be informed of any new findings that might affect your willingness to participate in these experiments as they arise.

Benefits of Participation
You might not benefit from being in this research study. The potential benefit to you from being in this study might be the free optometric screening both prior to and at the conclusion of testing.

New Study Findings
If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support
The University of Rochester is receiving payment from the National Institute of Health for conducting this research study.

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 an eye-tracking-only experiment. You will be paid $20 per hour for taking part in an EEG experiment. You will receive your payment after you complete all experimental sessions, or after each individual session. You will receive your payment in cash or by check.

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.

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, you will be assigned a random, unique number for identification purposes. This number will be used in identifying your data files and in all reports, publications, and references to you. The file that holds the association between your identifying information and your data files will be encrypted and kept separate from the computer where the data files are stored. 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 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

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 Institute 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 until the study is completed.

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.

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: Martina Poletti at (617) 358-1385.

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.

If you are a student at the University of Rochester, this will not affect your class standing or grades. You will not be offered or receive any special consideration if you take part in this research.

If you are an employee of the University of Rochester, 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.

****

SIGNATURE/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