

# **Participant Information Statement and Consent Form**

# Survey-based image grading of AMD biomarkers

Chief Investigators: Dr Matt Trinh, Dr Rene Cheung, Ms Cherlin Lee, Ms Ruhini Katuwanage

#### 1. What is the research study about?

You are invited to take part in this research study. The research study aims to determine the diagnostic accuracy of optometrists in using optical coherence tomography (OCT) and colour fundus imaging to identify lesions important for diagnosing and predicting the risk of age-related macular degeneration (AMD) progression. You have been invited because you are a qualified optometrist and your contact details were obtained from the UNSW School of Optometry and Vision Science administrative staff.

# 2. Who is conducting this research?

The study is being carried out by the following researchers from the UNSW School of Optometry: Matt Trinh, Rene Cheung, Ms Cherlin Lee, Ms Ruhini Katuwanage.

**Research Funder:** This research is supported by the Macular Degeneration Research Grant from the Estate of the late Peter Anthony John Vild and UNSW School of Optometry and Vision Science as part the Independent Learning Project for the UNSW Medicine Program.

#### 3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is okay for you to participate. The research study is looking recruit people who meet the following criteria:

- Inclusion criteria: Qualifications to practise optometry
- Exclusion criteria: none.

#### 4. Do I have to take part in this research study?

Participation in any research study is voluntary. If you do not want to take part, you do not have to. If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Complete the survey.

#### 5. What does participation in this research require, and are there any risks involved?

**Electronic survey:** If you decide to take part in the research study, we will ask you to complete an electronic survey at the Centre for Eye Health, UNSW, Sydney, or at your place of practice. The survey will ask you questions about your level of exposure to OCT and colour fundus photography in the workplace and then ask you to grade whether you can see specific biomarkers in de-identified patient images while wearing a gaze tracking device. It should take approximately 30 minutes to complete.

**Risks:** This is a low-risk research study as you will not be required to participate in any form of physical activity. You will also not be required to attend a screening interview. Instead, you will be given access to the survey upon agreement of partaking in this research study and fitted with a gaze tracker to record eye movements for the duration of the survey. We expect that participating in the research should not cause you more than mild discomfort. If, by any chance, you do become distressed during the research, please be aware that we have provided contact information for support services in section 10 of this document.





If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. You can also tell a member of the research team and they will provide you with assistance or alternatively a list of support services and their contact details are provided below.

#### 6. What are the possible benefits to participation?

We hope to use information we get from this research study to provide critical insights into how well optometrists can interpret key biomarkers on OCT and colour fundus photos to accurately diagnose and predict late AMD risk, and gaze patterns associated with improved detection. This can help pinpoint potential gaps in knowledge that could be addressed through continuing education programs. This will either validate the use of specific biomarkers for diagnosing and predicting the risk of AMD progression, or highlight areas that could be improved in future professional training events. You will receive a copy of the clinical cases annotated with the actual diagnoses and a certificate of attendance after the session to redeem up to 1 hour of interactive, non-therapeutic CPD, including the time to review cases.

#### 7. What will happen to information about me?

Submission of the questionnaire is an indication of your consent and provides your permission for the research team to collect and use information about you for the research study.

The research team will store the data collected from you for this research project for a minimum of 5 years after the publication of the research results. The information about you will be stored in a non-identifiable format. Participating in the study means that you provide consent for the information collected to be used for this research study and related future research studies.

#### 8. How and when will I find out what the results of the research study are?

The research team intend to publish and report the results of the research. All information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by emailing any of the researchers listed below. We will only use your email to send you the results of the research.

#### 9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do this by closing the survey. If you withdraw from the research, we will destroy any information that has already been collected. Once you have submitted the survey however, we will not be able to withdraw your responses as the survey is anonymous.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

# 10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:



# **Research Team Contact**

Name	Dr Matt Trinh	
Position	Research Study Supervisor	
Telephone	02 8115 0791	
Email	m.trinh@unsw.edu.au	
Name	Dr Dana Chaung	
name	Dr Rene Cheung	
Position	Research Study Supervisor	
Telephone	02 9348 1345	
Email	rene.cheung@unsw.edu.au	
Name	Miss Cherlin Lee	
Position	Student investigator	
Telephone	N/A	
Email	cherlin.lee@student.unsw.edu.au	
Name	Miss Ruhini Katuwanage	
Position	Student investigator	
Telephone	N/A	
Email	r.katuwanage@student.unsw.edu.au	
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# What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

# **Complaints Contact**

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	iRECS6107

If you experience discomfort or feelings of distress while participating in the research and you require support, you may contact support services such as **Beyond Blue**, ph 1300 22 4636.



# Consent Form - Participant providing own consent

# Declaration by the participant

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or it has been provided to me in a language that I understand;
- I provide my consent for the information collected about me to be used for the purpose of this research study.
- I provide my consent for the information collected about me to be used for the purpose of future related research studies.
- I understand that, if necessary, I can ask questions and the research team will respond to my questions.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that I can download a copy of this consent form from <u>PISCF Form (optometrists)</u> <u>15.4.25.docx</u>
- If you would like to receive a copy of the study results via email or post, please contact any of the above investigators via email.