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**PARTICIPANT INFORMATION SHEET**

**Psychophysics and Retinal Imaging**
Approval Reference: 2447/27342

1. ***Background and aims of the study.***

This study aims to functionally image the cone photoreceptor cells in the retina of the eye and characterise eye movements at unprecedented resolution. The aim of this study is to better understand the behaviour of the cone photoreceptor cells and involuntary fixational eye movements to different stimuli, including stimuli that are precisely controlled on the retina. This research will help further our understanding of the early stages of human vision: how the individual cells in our eyes respond to light, and how our eye movements may adapt to allow us to perform better in response to different tasks. This research will also help to characterise how these functions differ between people, taking into account age and self-reported health conditions.

This study is funded by the EPSRC Transformative Healthcare Technologies.

2. ***Why have I been invited to take part?***

You have been invited because you have normal or corrected-to-normal (with glasses or contact lenses and ideally a prescription of between -2 and 2 Diopters) visual acuity, do not suffer from epilepsy and are aged 18 years or over.

3. ***Do I have to take part?***

No. You do not have to take part. You can ask questions about the study before deciding whether or not to participate. If you do agree to participate, you may withdraw yourself from the study at any time, without giving a reason and without penalty, by advising the researchers of this decision.

4. ***What will happen in the study?***

The study will take place In the Henry Wellcome Building, Newcastle University.

If you are happy to take part in the study, you will be invited to attend a study visit which could last up to 5 hours. You may be asked to attend two study visits which can last 3 hours each. You will be able to take rest breaks as you need. Before the visit, you will be asked to complete a short questionnaire regarding your general health. This questionnaire will ask you to report your month and year of birth, gender, and ethnicity, and your/your relatives' colour vision, all of which may affect colour vision. It will also ask you whether you consider yourself to have any one, or more of the following health conditions: Parkinson's disease, Alzheimer's disease, Huntington's disease, Diabetes, High Blood Pressure, Strokes, Kidney Disease, Heart Disease/Angina, Thyroid Disease, Depression, Schizophrenia, Sleep Apnea, Cancer, Autism Spectrum Disorder, Attention Deficit/Hyperactivity Disorder). You will also be asked to report what medication you are currently taking. Such data is important as part of this study as we aim to understand how eye movements

vary between individuals, and certain health conditions may be confounding factors of interest in that variability. You may indicate prefer not to say for any or all options. If you report having Parkinson's disease, you will then be asked to complete the MDS-UPDRS (The International Parkinson and Movement Disorder Society (MDS) Sponsored Revision of the Unified Parkinson's Disease Rating Scale) as an indication of disease severity at the time of the study.

If you need glasses or contact lenses, may will ask you to wear them to the session. At the start of the session, you will be told about the study and have the opportunity to ask questions. Then the researcher will ask you to provide written informed consent to take part in the study before proceeding, and after receipt of written consent you will be asked to provide your pre-screening questionnaire, when applicable.

We will first ask you to read letters from a wall chart or monitor. During the session you will perform a task. This involves looking at a visual target on a computer monitor or adaptive optics corrected visual stimuli while your cone photoreceptor cells are being recorded by a retinal imaging system or your eyes are being tracked by a model-based eye tracker.

For recordings made with the retinal imaging system, the measurement of cone photoreceptor cells requires the head to be stabilised. Your head can be stabilised using two methods: a bite bar or a chin rest with supports. If we use a bite bar one will be created out of dental wax, which you will bite on during the session – we will try and make it as small as possible to ensure you are comfortable. If you are unable to use a bite bar, we will use a chin rest instead. This chin rest may have additional stabilisation support for your forehead.

Retinal imaging will be achieved with an instrument called an adaptive optics scanning light ophthalmoscope (AOSLO), which uses a low power light source to scan a patch of the retina. This allows us to image the photoreceptors in your retina while you are looking at a fixation target. This is a very precise instrument, and it will take between 10 and 30 mins to set up, during which we will take account of any spectacle or contact-lens prescription you might have. In some cases, the instrument cannot be set up correctly. This is no reflection on your eyesight but in this instance, we will not ask you to complete the study. For eye tracking done with a video-based eye tracker you will just need to place your head on a head rest which should only take 5-10 mins to set-up. Again, there may be some cases where the instrument cannot be set up correctly, which is no reflection on your eyesight, but in this instance, we will not ask you to complete the study.

While the duration of the session may last for up to 5 hours, each recording of your cone photoreceptor cells with the retinal imaging system or of your gaze position with the video-based eye tracker will only take several minutes, and there will be regular breaks between recordings and trials. You will have the option to pause the experiment as necessary. Sometimes multiple recordings will happen in one trial, with one trial typically lasting around 20 or 30 minutes, though some trials may have only one recording and only take several minutes.

### *5. Are there any potential risks in taking part?*

You should not take part if you suffer from epilepsy, because the tasks involve looking at simple visual targets that flash onto the screen, interspersed with flickering stimuli.

You may not wish to take part if…

… you're prone to migraines. This study involves sessions of up to 5 hours. A significant proportion of this time will be in a dark room looking at a display. However, we will offer you regular breaks during the study to ensure your comfort.

… you suffer from dry eyes, as the procedure we use for retinal imaging involves a light that some experience to be drying to the eyes. Light safety calculations have been performed and the amount of light we use is well below the maximum safe limit.

If we invite you to perform a visual acuity test, there is a risk that you might learn that you have atypical visual acuity, even if you have so far been unaware of it. If that is the case, we can give you a letter to take to an optician if you wish.

In order to keep you comfortable during the testing, the researchers will offer you regular breaks, and you can also ask to take a break at any time.

6. ***Are there any benefits in taking part?***
   There are no direct benefits to you.

***7. Expenses and payments***
You will be paid £12.50 per hour as gift card for taking part in this study (including for the half hour required to complete the pre-visit questionnaire with payment for this to be made upon completion of the first visit). We will also provide you with an image of the cone photoreceptors in your retina, if we are able to successfully capture an image, if you request one.

8. ***What happens to the data provided?***

**Research data.**
De-identified research data and records will be stored for a minimum retention period of 3 years after publication, in accordance with the University of Newcastle's Policy on the Management of Research Data & Records.

**Personal and special category data.**
There are different kinds of personal and special category data that we will collect, and each kind will be stored differently depending on the consent you provide and how the data will be used.

1) For every participant, the consent form containing your name and signature will be stored as a hard copy in a lockable cabinet in the Henry Wellcome Building for as long as the corresponding research data is stored.
2) For every participant, the de-identified screening records, including the pre-visit questionnaire answers with your age, biological sex, ethnicity, colour vision deficiencies, health conditions, and familial colour vision deficiency will be stored as both a hard copy in a lockable cabinet in the Henry Wellcome Building and typed into a computer document and saved to a password-protected encrypted drive. This data will be stored for as long as the research data.
3) If you give consent for us to contact you for future studies, you will complete a questionnaire with your name and email address. This will be stored as both a hard copy in a lockable cabinet in the Henry Wellcome Building and typed into a computer document and saved to a password-protected encrypted drive. This will be stored separately from any research data. This data will be destroyed 10 years after completion of the study.
4) If you give consent for us to store your contact details with your participant identifier code so that we may contact you for future studies and link your data from this study with data you may provide in future studies, your participant identifier code will also be noted on the questionnaire with your name and email address. This will be stored as both a hard copy in a lockable cabinet in the Henry Wellcome Building and typed into a computer document and saved to a password-protected encrypted drive. This will be stored separately from the research data. This data will be destroyed 10 years after completion of the study.

9. ***Data Protection***

Newcastle University is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest. Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

10. ***Will the research be published?***

The research will be submitted for publication in peer-reviewed journals and for presentation at scientific conferences. We may find your data useful for future research, in addition to the present study. If you are happy for your data to also be used in future, ethically-approved research, you can indicate this on the consent form.

11. ***Who has reviewed this study?***

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are internal to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.

12. ***Who do I contact if I have a concern about the study or I wish to complain?***

If you have a concern about any aspect of this study, please speak to Varun Padikal [V.P.Padikal2@newcastle.ac.uk] or the principal investigator Dr. Laura Young [laura.k.young@newcastle.ac.uk] and we will do our best to answer your query.
We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the chair of Faculty of Medical Sciences Research Ethics Committee at Newcastle University who will seek to resolve the matter as soon as possible:

Email **fmsethics@ncl.ac.uk**

13. ***Contact Details***

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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