PATIENT PARTICIPANT INFORMATION SHEET

Study Title: Visual Function in Retinal Degeneration

Chief Investigator: Professor Robert E MacLaren

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish.

If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The primary purpose of this study is to assess the usefulness and effectiveness of current and new visual assessments for use in patients with inherited retinal degeneration. The results will enable us to determine which tests are the most suitable for patients with a particular disease and disease stage. These tests are already approved tests but have not been used in specific types of retinal degeneration.

Why have I been invited?

You have been invited to take part in this study because you have an inherited retinal degeneration. A member of the research team will go through this information with you and answer any questions to help you decide if you would like to take part.

We are aiming to involve 40 participants with retinal degeneration and 40 healthy controls with no known visual problems other than a glasses prescription if required.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of hospital care you receive.

What will happen to me if I decide to take part?

The study requires undertaking additional visual assessments alongside the routine hospital clinical assessments at Oxford Eye Hospital. The study tests will take place on the same day as your routine outpatient hospital appointment, either beforehand and/or afterwards. We will consult your medical notes for relevant information, such as the specific genetic cause of your eye condition if available.

The study vision assessments include:

- Three questionnaires about your vision, how you feel about your vision and your quality of life
- A glasses correction check
- Visual acuity tests that involves reading letters on a letter chart
- Visual field tests that involves assessing the area extent of your vision.
- Visual field tests after 20 minutes of allowing the eyes to adjust to very low light

All tests are CE marked and will be used for their intended purposes – assessing visual function.

The study tests are split into two parts, part 1 and part 2. Part 1 involves the questionnaires about your vision and quality of life followed by several letter chart tests. Where possible the questionnaires will be sent to you in advance to allow you time to complete them. Part 2 involves a peripheral vision test undertaken in very low light.

Part 1 tests will take place around or before your routine clinical appointment, whereas part 2 is afterwards. To maximise the opportunity for individuals to get involved, there is some flexibility around whether you complete part 1, part 2 or both sections of the study. On average part 1 and part 2 each take about 60 minutes on top of your routine appointment. For those patient participants who undertake all the additional study tests, it will take about 120 minutes in addition to the routine clinical procedures e.g. imaging and the doctor examination, which normal takes around 120 minutes.

If you require glasses correction for distance vision is it helpful if you bring these to the study although not essential. If you wear contact lenses, you are still eligible to participate in the study but the contact lenses will need to be removed during the study assessments.

Following the study, some patient participants will be invited (either by email or telephone) to take part in a voice recorded telephone interview, at a mutually agreed time. This will usually be within 48 hours of completing the study. This is optional and you can opt out on the study consent form. The purpose of the interview is to gain greater understanding of how you found the different tests, how they made you feel and whether there are changes you can recommend to improve the testing or study experience. We anticipate that the interview will last about 45 minutes, however it may be longer if you need more time

to discuss your thoughts or feelings. All information from the recordings will be anonymised. The digital voice recording will be transcribed into text to enable analysis, this will be carried out by a University of Oxford approved 3rd party. We may use anonymous quotes from the interview in the publication of our findings.

What will happen if I do not want to carry on?

You have a right to withdraw from the study at any time, without giving a reason, but we will keep information about you that we already have.

What are the possible risks of taking part?

There are no direct risks to taking part. This is because the vision tests are non-invasive and do not pose any hazards. If you become tired during testing, you will have the opportunity to stop and rest before continuing with testing. There is a very small chance of finding an unexpected abnormal result. If this happens, we will flag this up to the consultant in charge of your eye care to investigate further.

What are the possible benefits of taking part?

There are no direct benefits of taking part in this research project. However, by taking part, we hope you will be contributing to improving our understanding on how to best measure vision in people affected by a retinal disease. The outcomes of this study may play a role in helping patients in the future, and in the development of effective treatments or services.

Will my part in this study be kept confidential?

All information, which is collected, about you during the course of the research will be kept strictly confidential. If you decide to participate, only initials and an ID number will identify you. Only the consent form will contain your name and email, this will be stored securely in a locked filing cabinet, and will only be accessible by authorised personnel. The study will comply with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. The data will be archived in a secure facility for 3 years from the end of the study.

Responsible members of the University of Oxford and the Oxford University NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

No, there will be no reimbursement.

What if we find something unexpected?

If an unexpected result is found these findings will be flagged up to the consultant or doctor overseeing the clinic.

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the data controller and is responsible for looking after your information and using it properly. We will keep identifiable information about you for three years after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for also three after the end of the study.

UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

The interview audio recordings will be stored securely on the University of Oxford network under password protected files and deleted immediately off the audio recording device. Anonymised data will be shared with the 3rd party approved transcriptionist. No identifiable data will be shared with the approved 3rd party. In addition, prior to the sharing of recorded audio data, a signed agreement with the approved 3rd party transcriptionist will be in place, preventing any sensitive information being shared to anyone outside the study. The data sharing will take place via a secured University of Oxford data sharing programme, the transcriptionist will transfer the audio recording into a written format and return to us. They will not retain any data once the transcription is complete. The anonymised audio data and transcriptions will also be kept for three years after the end of the study in case they need to be reviewed. We may publish anonymised quotes from the interviews in any of the final research publications.

What will happen to the results of this study?

At the end of the study the anonymised results, including your genetic data and ocular imaging, will be analysed and published in the medical literature and presented at conferences. Anonymised research data gathered may contribute to the fulfilment of an educational requirement (e.g. an MSc thesis). You will not be identified in any report/publication.

If you would like to be notified about the results of the study, please indicate this on the consent form.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of any clinical treatment, which is provided. Given the observational and non-invasive nature of this study, it is highly unlikely that you will suffer harm by taking part.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Laura Wood at trials@eye.ox.ac.uk or 01865 231122, or you may contact the University of Oxford Research Governance, Ethics & Asurrance (RGEA) office on 01865 616480, or the director of RGEA, email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. You will be able to contact the Patient Advice and Liaison Service (PALS) in the first instance (01865 221473). PALS is unable to provide information about this research study.

Who is organising and funding the study?

The study is being organised by Laura Taylor from the Nuffield Laboratory of Ophthalmology and sponsored by the University of Oxford. The study is funded by the NIHR Research for Patient Benefit tier 3 fund.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Black Country Research Ethics Committee.

Further information and contact details:

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Thank you for reading this information sheet