



## **Project title: Comparison of Progressive Power Lenses**

### **PARTICIPANT INFORMATION SHEET**

#### **Principal Investigator:**

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#### To the Participant

I am an academic staff member in the School of Optometry and Vision Science at the University of Auckland, and I am investigating the performance of two spectacle lens designs.

I am carrying out this research on behalf of an international lens design and manufacturing company. This company designs and manufactures lenses for worldwide markets and wishes to know how a new design of progressive lens performs in comparison with an existing lens design when used by people in New Zealand. This company is funding this study.

I am seeking volunteers to participate in this study who are over the age of 41 years, who are free from, and do not have a history of eye disease, and who have been wearing progressive lenses for constant use for at least one (1) month with wear times of more than 5 hours per day.

If you agree to participate, you will be provided with a set of spectacles with the first pair of progressive power lenses to your prescription to wear for at least 15 days prior to the lens comparison period. You will be able to keep these spectacles at the end of the study.

During the lens comparison period you will be provided with other pairs of lenses (also to your prescription) in an identical frame. There will be two other pairs of lenses and you will be asked to wear each pair of lenses for more than 5 hours per day for a 14-day ( $\pm 3$  days) period.

At the beginning and end of each 14-day period we will measure your visual acuity using letter charts and make measurements to ensure that your prescription is supplied accurately. These measurements are the same ones that are used routinely in the supply of every pair of prescription spectacles.

At the end of each 14-day period we will ask you to complete a questionnaire (estimated time to complete less than 15 minutes) that will ask you about your experiences with the different sets of lenses.

The lens comparison period can begin only when the new design lenses manufactured in your prescription are received from the Europe Research and Development division of the sponsoring company. There could be a delay of a several weeks while these are delivered to Auckland.

There are no risks of adverse reactions in this study. There is no audio or videotaping.

In summary if you agree to participate, there will be five visits (each of 30 to 45 minutes duration). The delay between the first and second visits will be about two weeks. The delay between visit 2 and visit 3 will be at least 15 days but may be a several weeks more. The final three visits must be at 14-day ( $\pm 3$  days) intervals.

At the end of each visit during the study, we will provide you with a \$40 gift voucher to assist you with the costs of travel and parking during the study for each of the 5 visits.

At the end of the study, you will be able to keep the first pair of glasses. Note: As the second and third pairs of progressive spectacles worn during the lens comparison (investigative) part of the study must be returned to the sponsor for identification, these cannot be offered to you even if one or other of them happened to provide improved comfort.

Your identity will be coded so that data from the study cannot be linked to you personally. The link between your identity and the code is held in confidence by the University of Auckland investigators and is not supplied to the sponsoring company. The coded data and the data key will be kept in securely by us for 6 years. After that time, it will be destroyed and will not be used in any future research.

The anonymised data collected during the study is supplied to the sponsoring company as soon as it is collected. Should the anonymous results of the project be reported in the scientific literature no individually identifying data will be included in the publication.

The spectacle frame style used for the lenses is of your choosing with the limitation that three identical frames must be available so that you can receive the next pair of lenses without delay. Should you wish to choose a spectacle frame style over \$400 in retail price, we will ask for a co-payment from you to cover the extra price over \$400.

At the end of the study your ongoing care will be returned to the staff of the University Optometry Clinic or to your usual optometrist.

Participation in this project is completely voluntary.

In order to keep your identity absolutely anonymous, NO information can be withdrawn from the study once it has been provided by us to the sponsoring company. This occurs usually on the day of your visit or by Friday each week.

Should you be unable to complete the study, your data (although incomplete) and the reasons for your withdrawal will remain in the study and you will still receive the initial pair of prescription spectacles.

Should you wish to withdraw from the study without giving a reason, we will be pleased to help you choose another frame and lens design so that your prescription can be filled just as it would have been had you not entered the study. Your care would then be returned to the University Optometry Clinic or your usual optometrist and normal clinic charges for the spectacles would apply.

There will not be any penalty or loss of benefits regarding the services provided to you by the University of Auckland Optometry Clinic should you decide not to participate in this project or should you decide to participate in this project.

Should you agree to participate in the study, your optometrist will be informed (with your consent) that you are taking part in this study.

During your participation in this project, there is a very small possibility that your results will show that your visual acuity is changing. If this is found it may indicate the presence of an eye disease about which you and we were previously unaware. In the event of this, these “incidental findings” will be treated as they would be in a normal optometric examination. Appropriate management will be employed, which may involve referral to the University Optometry Clinic, to your usual optometrist, or to an ophthalmologist or other specialist.

Thank you very much for giving your time to consider participating in this project. If you have any questions about this project, do not hesitate to contact us.

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If you require Māori cultural support, talk to your whānau in the first instance. You may also contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324, or contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 4868920 ext 3204 to discuss any questions or complaints about the study.

For any queries regarding ethical concerns, you may contact the Chair, The Auckland Health Research Ethics Committee, The University of Auckland, Office of the Vice Chancellor, Private Bag 92019, Auckland 1142. Telephone 09 373-7599. Email [ahrec@auckland.ac.nz](mailto:ahrec@auckland.ac.nz).

**Approved by the Auckland Health Research Ethics Committee on 7/4/21 for three years.  
Reference number 2021/21854.**