

Precision Tinted Lens Prolonged User Panel

Introduction to the Prolonged User Panel

1. The purpose of the Precision Tinted Lens Prolonged User Panel is to provide volunteer participants for research using precision tinted lenses (PTL)
2. The Panel was established and is administered by:
Professor Bruce Evans
Professor Arnold Wilkins
Professor Peter Allen
3. Applications by researchers who wish to use the panel in their research studies should be made to admin@ioo.org.uk.
4. Applications to use the panel will be considered according to the 7 principles for ethical research outlined at www.bioethics.nih.gov/education/FNIH_BioethicsBrochure_WEB.PDF
The 7 principles are scientific validity, social value, fair participant selection, good risk-benefit ratio, independent review, informed consent, and respect for participants. Applications to use the panel will be required to confirm that they have received approval from an appropriate Research Ethics Committee.

Eligibility criteria for membership of Prolonged User Panel

1. Aged at least 18 years
2. Using PTL for at least 6 hours a week or most of the time when reading by self-declaration
3. Meet criterion 2 for at least 2 years

Recruitment to Prolonged User Panel

1. The Prolonged User Panel will be publicised to all eyecare practitioners using an Intuitive Colorimeter through publicity from the manufacturers, Cerium Visual Technologies.
2. The Panel may also be publicised to other groups, for example the Society for Coloured Lens Prescribers (S4CLP) and the International Institute for Colorimetry.
3. Practitioners will be invited to download the attached Information Sheet and Consent Form to give to patients who are eligible. Patients can then send this to the address given on the form if they consent to be on the panel.
4. It is stressed that it is up to the practitioners to obtain their patients consent for this research and to make a decision if this is suitable for their patients. It is entirely voluntary for practitioners to decide whether to pass the information to their patients and for patients to decide whether they wish to consent to participate.

PRECISION TINTED LENS PROLONGED USER PANEL PARTICIPANT INFORMATION SHEET

You are being invited to join the Precision Tinted Lens Prolonged User Panel. Before you decide it is important for you to understand what the Panel is and your involvement if you decide to join the panel. Please take time to read the following information carefully and discuss it with others or with one of the panel if you wish. Take time to decide whether or not you wish to join.

What is the purpose of the Panel?

Precision Tinted Lenses are coloured lenses that are individually prescribed to alleviate symptoms of eyestrain, headaches, and visual perceptual distortions. They are used in a condition called visual stress (Meares-Irlen Syndrome, previously known as scotopic sensitivity syndrome). Visual stress may be associated with reading difficulties (e.g., dyslexia), migraine, epilepsy, autism, multiple sclerosis, and stroke.

There have been several research studies to investigate visual stress but, as with many other conditions, there is a need for more research to better understand the condition. One way of studying visual stress is to investigate people who are believed to have the condition and the Prolonged User Panel has been established to facilitate this.

Why have I been chosen?

Your eyecare practitioner has identified you as someone who is eligible to join the Prolonged User Panel. The eligibility criteria are that you must be at least 18 years old and have used precision tinted lenses for at least two years and wear them at least 6 hours a week or most of the time when reading. If you use them most of the time when reading and also at other times then you would still be eligible.

Do I have to join the Panel?

No, it is entirely up to you to decide whether or not to join the Panel. If you do 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 from the Panel at any time and without giving a reason. A decision to withdraw or a decision not to join the Panel or not to take part in any research, will not affect in any way your standard of care at this practice.

What will happen to me if I join the Panel?

If you join the Panel then your details will be stored, both on paper and electronically in accordance with the Data Protection Act. You will **not** receive confirmation and it is anticipated that you will **not** receive regular contact about the Panel.

If researchers wish to use the Panel for their research then they have to apply to the academics who established the Panel (Professor Bruce Evans, Professor Arnold Wilkins, and Professor Peter Allen; described below as the Panel administrators). These three administrators of the panel vet applications to decide if the research is likely to be a worthwhile and reasonable use of the time of members of the Prolonged User Panel. The administrators will make sure that the research study has received approval from a Research Ethics Committee. If the

research is suitable then your details may be passed to the researchers who will contact you.

If you are contacted by researchers then they must give you full information on their research and you will have the option of declining to participate in the research. If you decide that you would like to participate then you will be asked to sign a consent form that is specific to that study. If you have any questions about the research then you should direct these to the research team (not to the Prolonged User Panel administrators). If you have any complaints about the research then you should direct these to the research team for that study, but please also send a copy to the panel administrators (at the address below).

Research studies that are approved for using the Prolonged User Panel are likely to have their own selection criteria. For example, a study might only be interested in people of a certain age. It is therefore possible that you will join the Panel and not receive any invitations to participate in research.

What do I have to do?

If you decide that you would like to join the Prolonged User Panel then please complete the Consent Form below and forward it to the address indicated on the Consent Form.

Will my membership of the Panel be kept confidential?

All information that you provide to us will be kept strictly confidential in accordance with the Data Protection Act 1998. Information that includes your personal details will only be passed to researchers who are carrying out suitable research. Any information about you which is shared with others will have your name and address removed so that you cannot be recognized from it.

Contact for Further Information

Professor Bruce Evans, Institute of Optometry, 56-62 Newington Causeway, London, SE1 6DS; admin@ioo.org.uk.

CONSENT FORM

Precision Tinted Lens Prolonged User Panel

- I have read the attached information sheet and have been given a copy to keep.
- I understand that my personal involvement in the Panel and my particular data will remain strictly confidential.
- I have been informed that my details may be passed to researchers who are carrying out studies that require access to the panel.
- I understand that if I am invited to participate in a research study then I do not have to say yes and if I do decide to participate then I will be free to withdraw at any time.
- I understand that I am free to withdraw from the panel at any time, using the contact details below. I do not have to give a reason for withdrawing.
- I hereby fully and freely consent to join the Prolonged User Panel.

Name (Block Capitals):..... Date:.....

Signature:.....

Please could you provide the following information:

Gender: male/female Date of birth: Email:.....

Address:.....

..... Telephone:.....

When did you first start using precision tinted lenses?.....

Approximately how many hours do you use precision tinted lenses in an average week?.....

Please underline the activities for which you normally use precision tinted lenses:

Reading or writing / computer work / television / school / office / driving / other (detail below)

Detail of other:.....

Please underline any of the following conditions that you believe you suffer from:

Specific learning difficulties / dyslexia / autism / migraine / epilepsy / multiple sclerosis / stroke /
other (detail below)

Detail of other:.....

Please send this form to:

Professor Bruce Evans

Institute of Optometry

56-62 Newington Causeway

London

SE1 6DS

Thank you