School of Optometry and Vision Science

UNSW SYDNEY

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Can your eyes feel the cold? – Evaluation of ocular sensitivity using a cold stimulus

Professor Fiona Stapleton

1. What is the research study about?

You are invited to take part in this research study because you have expressed interest to our recruitment advertisement. The research study aims to look at the surface of the eye and explore how the cold thermoreceptors, specifically respond to cooler temperatures with the use of the Liquid Jet Aesthesiometer. The Liquid Jet Aesthesiometer is a device that can measure the sensitivity of the eye with micro jets of saline. You have been invited to take part in this study to help us better understand what the role of cold receptors are in eye discomfort. Further down the track, the results obtained may be applied in the eye care clinics, to assist with the diagnosis and management of conditions and diseases affecting the eye's surface.

2. Who is conducting this research?

The study is being carried out by the following researchers: Prof. Fiona Stapleton, Associate Professor Blanka Golebiowski, Associate Professor Klaus Ehrmann, Dr. Yoshiaki Tagawa and Dr Nidhu Sivankhutty-at The School of Optometry and Vision Science.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that you are suitable to take part. The research study is looking to recruit participants who meet the criteria listed below. Participants will:

- Be able to read and understand English
- Be aged between 18 and 40 years old
- Not wear contact lenses on the day of the visits
- Be non-contact lens wearers OR soft contact lens wearers of at least 5 hours wear for at least 5 days a week

Participants are not suitable if they:

- Have ocular or systemic conditions affecting their ocular sensations (For example Graves' disease, diabetes, Sjogren's syndrome, multiple sclerosis)
- Have any active eye infections or inflammation
- Use any eye and/or general medication which are known to affect eye health and symptoms, such as chloramphenicol, prednisolone acetate, accutane and antidepressants for one week prior to the study and/or during the study
- Have a previous history of eye surgery like corneal refractive surgery and cataract surgery
- Are currently pregnant or breastfeeding
- Are currently wearing contact lenses in the extended-wear modality, ie. continuous day-and-night wear without removal
- Are currently wearing contact lenses on an intermittent or part-time basis, of less than 5 hours per day, 5 days per week.
- Are current or previous wearers of hard contact lenses, including Ortho-K lenses

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

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

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);

- Sign and return the consent form;
- Take a copy of this form with you to keep.

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

If you decide to take part in the research study, we will ask you to attend four sessions, all conducted over the course of a one hour visit, as detailed below.

Session 1 - Baseline (20mins)

- After consent has been given, screening questions for inclusion in the study will be asked by going through section 3 of this form.
- Two questionnaires about ocular symptoms will be then given to you to fill out.
- Your current vision will be measured on a chart.
- You will have the front of your eye examined with slit lamp biomicroscopy to detect possible signs that may exclude you from this study.
- You will be positioned on a chin rest in front of the Liquid Jet Aesthesiometer and the room lights will be turned off. You will then be directed to look at a light on the wall behind the examiner. A demonstration run of the Liquid Jet Aesthesiometer will be administered in one eye for you to familiarise yourself with the instrument. Micro volumes of sterile phosphate buffered saline will be projected onto the front surface of the eye at randomised time intervals. You will be given a buzzer to press to indicate when a sensation has been felt.
- A measurement will then be administered on the other eye at three locations, the cornea, conjunctiva and your lid margin. The order of these measurements will be chosen randomly. The measurement is taken the same way as the demonstration but you will also be fitted with earmuffs to mask the sound of the instrument dispelling the liquid. The measurement should take approximately 10-15 mins.
- You will be able to take breaks between the sessions

Session 2 - Test 1 (10mins)

- The sensitivity at the first location (cornea, conjunctiva, or lid margin) will be measured with the Liquid Jet Aesthesiometer.

Session 3 - Test 2 (10mins)

- The sensitivity at the second location (cornea, conjunctiva, or lid margin) will be measured with the Liquid Jet Aesthesiometer.

Session 4 - Test 3 (20mins)

- The sensitivity at the final location (cornea, conjunctiva, or lid margin) will be measured with the Liquid Jet Aesthesiometer.
- You will have the front of your eye examined again with slit lamp biomicroscopy to ensure no damage has occurred to your eye during the procedures.

The risks involved in this research are minimal and extra measures have been put in place to reduce the possible risks even further. As participants will have their visual and auditory senses muted with earmuffs and dark room lighting in order for us to control external factors influencing the results, there is the possible hazard of tripping. To minimise this, you will be seated and carefully instructed about the procedure before earmuffs are put on and room lights are turned off.

Another possible risk factor is discomfort when the saline touches the eye's surface. This will be minimised by careful explanation of the process so that you are aware of what to expect.

A very unlikely risk is the possibility of an infection of the eye. However, this risk will be managed by ensuring the solution used in the procedure is sterile saline. The instrument will also be disinfected at least once every 7 days with 5% Sodium Hypochlorite and purged with distilled water, air and the phosphate buffered saline multiple times to ensure that there no sodium hypochlorite remains within the instrument.

We do not expect the questionnaires, slit lamp examination or Liquid Jet Aesthesiometer measurements to cause any harm or discomfort. If you do 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. Alternatively, a list of support services and their contact details are provided below on page 5.

6. What are the possible benefits to participation?

While there is no personal gain or benefit to the participant, we expect the outcomes of this research to provide more insight into the areas of eye sensation and discomfort. Ultimately, we hope the information from this research to contribute towards new methods of diagnosis and treatment of conditions and diseases affecting the eye surface.

7. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about you for the research study. Your data will be kept for 7 years after the project's completion.

We will store information about you in a deidentified format and it will only be accessible by the investigators of the study. Paper records of pre and post measurement assessments of vision and corneal integrity will be stored in a secure locked filing cabinet at the School of Optometry and Vision Science. Electronic records collected on the laptop connected to the LJA as well as collated data on an

Excel spreadsheet, will both be stored within password protected devices. This data will be backed up weekly onto the university network drive and stored in a password protected folder.

Data collected will be used for this study's purpose and potentially in future studies too, if the participant provides consent by checking the boxes on the lower half of the consent form on page 6. Data will be stored electronically by the chief investigator, who will act as the custodian of the data bank. Custodian of the data will only disclose data to researchers requesting access after evidence of ethics approval is shown. Participants may withdraw consent for the data to be used in future projects at any time by contacting the custodian of the data bank, details on page 8.

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 complaint 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.

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

The research team intends to publish and report the results of the research study in a variety of ways. All information published will be done 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 including your details in the space provided in the consent form.

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 so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or the School of Optometry and Vision Science.
If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project.

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:

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Research Team Contact Details

Name	Dr Yoshiaki Tagawa
Position	Visiting Fellow
Email	y.tagawa@unsw.edu.au
Name	Dr Nidhu Sivankhutty
Position	Visiting Fellow
Email	n.sivankhutty@unsw.edu.au
Name	Professor Fiona Stapleton
Position	Chief Investigator
Email	f.stapleton@unsw.edu.au

Investigators have the necessary expertise/experience to assist participants of this research. More complex queries will call for a referral for consultation with the Chief Investigator.

Additional Services

- **UNSW Red Eye Clinic**
  Ground Floor,
  Rupert Myers Building (North Wing)
  Gate 14 Barker Street
  UNSW, Sydney NSW 2052
  Tel: (02) 9385 6859

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	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	**HC190593**

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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 someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of the research described in the study;
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- 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 would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

  Name: _____

  Address: _____

  Email Address: _____

- I understand that I will be given a signed copy of this document to keep;

Optional:

- ❑ I provide my consent to have my data used for future research purposes;
- ❑ I understand that this information will be used for future research purposes in deidentified format and my privacy will never be breached;
- ❑ I understand that this consent is separate to the study that I am agreeing to participate in and understand that providing my consent to have my data used for future research purposes is optional;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

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Declaration by Researcher*

- I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, and the School of Optometry and Vision Science. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Prof. Fiona Stapleton
Email:	f.stapleton@unsw.edu.au
Phone:	+61 2 9385 4375
Postal Address:	Rupert Myers Building Barker Street Kensington NSW 2033