PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

The role of the microbiome in dry eye

Dr Jerome Ozkan

1. **What is the research study about?**
   You are invited to take part in a research study, sponsored by Johnson & Johnson Vision Care, to investigate whether people with conditions that cause dry eye, such as meibomian gland and/or lacrimal gland dysfunction have different types of bacteria present on their conjunctiva (white part of the eye) and eyelid margins compared to a heathy group with no dry eye. This consent form describes the study and your role in it. Dr Ozkan will answer any questions you have about this study or this consent form. We ask that you read this form carefully and ask any questions you have regarding the information it contains.

   You have been invited because your records at the School of Optometry and Vision Science Clinic indicate you may have meibomian gland and/or lacrimal gland dysfunction. Your details were obtained from the clinic database. You may also be part of this research if you are healthy and have no meibomian gland dysfunction or dry eye.

2. **Who is conducting this research?**
   The study is being carried out by the following researchers:
   Dr Jerome Ozkan - Chief Investigator, School of Optometry and Vision Science, University of New South Wales (UNSW).
   Prof Mark Willcox – Director of Research, School of Optometry and Vision Science, UNSW.

   Research Funder: This research is being funded by Johnson & Johnson Vision Care Inc (USA) and the School of Optometry and Vision Science UNSW. Dr Ozkan is also funded by an NHMRC Research Fellowship.

3. **Inclusion/Exclusion Criteria**
   Before you decide to participate in this research project, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:
   - Must be at least 18 years of age
   - Have not worn contact lenses in the past 3 months
   - [Meibomian gland dysfunction group] Have been diagnosed with mild to moderate meibomian gland dysfunction, either with or without lacrimal gland dysfunction
   - [Healthy group] Do not have meibomian gland dysfunction or dry eye
   - Have not had any eye trauma or eye surgery (including previous cataract or corneal refractive surgery)
   - Must not be using any systemic or topical antibiotic, anti-inflammatory, immunosuppressive medication, over the counter drops containing preservatives and also topical glaucoma medication in the past 3 months.

4. **Do I have to take part in this research study?**
   Participation in any research project 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 project 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);
   - If you would like to participate, sign the consent form and;
   - Take a copy of this form home with you to keep.

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

Currently it is not known whether individuals with meibomian gland dysfunction and/or lacrimal gland dysfunction have different types of microbes compared to healthy individuals and how these differences correlate with dry eye signs, symptoms and severity. To achieve this, we will swab the conjunctiva and eyelid margin of both your eyes at three different visits to sample the bacteria present at these sites over time. The research visits, including the completion of the questionnaire and swab samples, will be done at the School of Optometry and Vision Science, UNSW, Kensington. All visits will be conducted between 9am and 5pm. The swabs will be sent to the laboratory for analysis of the level and types of microbes that are present. The cost of swabs and medical procedures completed during your study will be covered by the research team.

Before you begin any procedures, we need to do some tests to determine if you are suitable for the study. To do this we will assess your eyes at the initial visit to determine your suitability for the study. If you are suitable, you will be allocated into one of three groups as determined by Dr Ozkan, based on the clinical appearance of your eyes at the initial visit as follows:

Group 1: Meibomian gland dysfunction, without lacrimal dysfunction

Group 2: Meibomian gland dysfunction, with lacrimal dysfunction

Group 3: Healthy eyes (no meibomian gland dysfunction or lacrimal dysfunction)

You will then be required to return for an additional three (3) visits over the next 3 months (refer to Table 1 for visit schedule).

Table 1: Visit Schedule

Visit #	**Procedures**	**Location**	**Visit Length**
Visit 1: Screening	• Questionnaire • Assess ocular surface health • Assessment of meibomian gland function - tear break-up time - corneal/conjunctival staining - meibography • Assessment of lacrimal gland function - phenol red thread test	School of Optometry and Vision Science, UNSW	30 minutes
Visit 2: Baseline (BL)	• Assess ocular surface health • Swab of conjunctiva and eyelid margin	School of Optometry and Vision Science, UNSW	10 minutes
Visit 3: 1 month from BL	• Assess ocular surface health • Swab of conjunctiva and eyelid margin	School of Optometry and Vision Science, UNSW	10 minutes
Visit 4: 3 months from BL	• Assess ocular surface health • Swab of conjunctiva and eyelid margin	School of Optometry and Vision Science, UNSW	10 minutes

The specific procedure to be conducted at each visit:

 # Questionnaire
You will also be asked to complete a short questionnaire at the intial visit to assess your dry eye symptoms. We expect the questionnaire to take up less than 5 minutes.

 # Assessment of ocular health
Description: Use of a powerful lens and light (biomicroscope) to examine the front surface and structures of the eye
Risk: Apart from the slight discomfort of a bright light, the risk of physical injury with this examination procedure is extremely unlikely as it is a standard procedure used in research and general optometric practice to exam the ocular surface and eye lids.

 # Assessment of meibomian gland function
Description: The ocular surface and tears are assessed by instilling a harmless fluorescent dye (fluorescein) using a sterile strip impregnated with fluorescein and moistened with sterile saline and then assessed with a biomicroscope. The meibomian glands will then be assessed by application of mild finger pressure on the eyelid margin to observe the fluid expressed from the meibum gland and an image will be taken with a meibographer to determine how many glands in your lid are functional.
Risk: The risk of physical injury with this examination procedure is extremely unlikely as the only contact made is with the eyelid margin and the meibographer only takes an infrared image of your eyelid without any physical contact and it is a common instrument used in research and general practice to examine the eyelid health.

 # Assessment of lacrimal gland function
Description: Phenol Red Thread Tear Test - a commercially available test which uses a sterile fine thread of cotton treated with a pH indicator to measure the amount of tears being produced by the eye. The end of the thread is gently placed over the lower lid for 20 seconds and then removed. The length of thread which has changed colour to red is measured.
Risk: This test may cause a slight itchy sensation where it contacts the lower lid. Once the thread is removed the sensation should stop immediately. There is minimal risk of physical injury with this procedure as it is a standard procedure used in general optometric practice to assess the volume of tear secretion.

 # Swab of conjunctiva and eye lid margin
Description: Sterile swab passed across the surface of the conjunctiva (white part of eye) and the eyelid margin
Risk: The risk of physical injury with this procedure is rare as the swab is passed gently across the surface of the conjunctiva (white part of the eye) and eyelid margin. A separate swab is used for the conjunctiva and eyelid. You may feel a slight discomfort/scratchy sensation as the swab makes contact with your conjunctiva and even less sensation as the swab makes contact with your eyelid margin. Once the swab has been completed you may feel nothing at all or a slight, transient itchy sensation.

We don't expect the questions asked or procedures performed during the consultations to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance. Alternatively lists of services are provided in the contact details below to assist you if necessary.

6. **Will I be paid to participate in this project?**
You will be provided with $30 for the initial screening visit and $20 for each of the three scheduled follow-up study visits in the form of Coles/Myer gift cards on completion of each visit, to compensate for your time and expenses associated with attending the research study visits.

7. **What are the possible benefits to participation?**
You will not receive any direct medical benefit from participating in this study. However, the possible benefits to humanity include information about the complex microbial community that resides on the ocular surface and eyelid of people with dry and healthy eyes. We hope to use information we get from this research study to further understand the role of bacteria in dry eye disease.

8. **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. In accordance with the UNSW retention periods for records relating to research without potential long-term effects, we will keep your data for a minimum of 7 years after the projects' completion, after which it will be destroyed. We will store information about you in an unidentifiable format at the University of New South Wales School of Optometry and Vision Science. Your information will only be used for the current research project and all information obtained will be de-identified.

Researchers at UNSW are required to store their any aggregated data in the UNSW data repository, this is a system called ResData. Once the aggregated data is deposited into this repository it will be retained in this system permanently. It will, however, be retained in a format where your identity will not be known.

It may be necessary for Johnson & Johnson Vision Care Inc. to disclose your non-identifiable personal data to third parties involved in the study, such as companies affiliated to Johnson & Johnson Vision Care Inc., clinicians, sponsors, research staff, clinical research agencies and government licensing and health authorities. Some of these third parties may be located in Australia (Therapeutics Goods Administration) and outside of Australia, particularly in the United States of America (U.S. Food and Drug Administration), Asia and Europe as is the case with Johnson & Johnson Vision Care Inc. By agreeing to participate in this study, you are giving your permission:

1. for Johnson & Johnson Vision Care Inc. to process and verify your non-identifiable personal and sensitive data for purposes related to this study; and
2. for Johnson & Johnson Vision Care Inc. to disclose such non-identifiable data to third parties and to transmit such data to countries outside of Australia.

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 compliant 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**.

9. **Medical treatment compensation**
Every reasonable precaution will be taken to ensure your safety during the study. If you are injured as a direct result of your participation in the study, reasonable medical treatment will be provided. The cost of this treatment will be paid by the University of New South Wales.

Your participation in this study will not affect any other right to compensation that you might have under statute or common law.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards seeking compensation for injury.

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

The research team intend 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 adding your email within the consent form. We will only use these details to send you a summary of the research results after the study has been completed and the results have been published.

11. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw from the research 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 email or telephone the research team and tell them you no longer want to participate. If you decide to leave the research study, the researchers will not collect additional information from you. Your decision not to participate in the research will not affect your relationship with the School of Optometry and Vision Science, the University of New South Wales or the research team.

12. 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 want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Dr Jerome Ozkan
Position	Chief Investigator
Telephone	(02) 9385 9227
Email	j.ozkan@unsw.edu.au

What if I have a complaint or any concerns about the research study?

If you have any complaints about any aspect of the project, the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC190612

Consent Form – Participant providing own consent

Declaration by the participant

- I understand I am being asked to provide consent to participate in this research project;
- 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 project;
- I understand that the research team will collect swabs of the conjunctiva and eyelid margin; I provide my consent for this to happen.
- 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 project 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;

☐ I agree for my non-identifiable data to be provided to Johnson & Johnson Vision Care and companies affiliated to Johnson & Johnson

☐ I agree for my non-identifiable data to be provided to third parties which may include transmitting the data outside of Australia.

Participant Signature

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

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.

Form for Withdrawal of Participation

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

Participant Signature

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

The section for Withdrawal of Participation should be forwarded to:

Principal Investigator Name:	Dr Jerome Ozkan
Email:	j.ozkan@unsw.edu.au
Phone:	(02) 9385 9227
Postal Address:	Level 3, Rupert Myers Building, Gate 14, Barker St University of NSW, Sydney, 2052