Participant Information Sheet

Study title: **Inflammatory markers in dry eye disease and uveitis**

Department of Ophthalmology — Ethics committee ref: **21/STH/154**

Faculty of Medical & Health Sciences
University of Auckland

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You are invited to take part in a study on dry eye disease and uveitis. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study and what your participation would involve. Also, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.
This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

You are invited to participate in a research project to study swelling in front part of the eye due to dry eyes and uveitis .

One part of the study will involve examining patients with dry eyes. A second part of the study will involve assessing participants with uveitis. Participants with no eye disease will also be examined for comparison.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to participate in this study either because you have dry eyes or uveitis or no eye disease (as a control participant). The study will mainly be conducted in the Eye Clinic, situated at the University of Auckland, Grafton campus. If you agree to take part in this study, you will be seen once. Each visit will require about 40-60 minutes of your time.

Various features of the eye's surface will be observed using standard clinical techniques that are performed routinely for assessing dry eye. These include:

1. Grading of ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using brief, validated, dry eye questionnaires (taking a total of 10 minutes to complete).
2. Examination of the anterior eye, including the eyelids, eyelashes and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms, as well as the Oculus Keratograph 5M and the E-Swin TearCheck device. These are commercially available devices used routinely in the clinical setting and do not directly touch your eye. Evaluation of tear film height and quality is assessed from very high magnification images in which you are not individually identifiable.
3. The quantity and quality of the eyelid gland contents will be assessed following gentle pressure applied to your closed lower eyelid (equivalent to that of a forceful blink).
4. Clinical evaluation of tear osmolarity, using a device which can feel ticklish on your eyelashes but doesn't touch the ocular surface.
5. The clear, front part of your eye will be examined using a different, high magnification microscope. You will need to place your chin and forehead in a similar way to the previous computerized tests. Numbing drops will be put in your eye and you won't feel anything. Photographs of your eyes will be taken by a special microscope.
6. Tears will be collected using a specialised technique from corner of your eyelids after putting some saline eye drops. This is called flush technique. You may feel ticklish but it does not cause any discomfort.
7. Evaluation of the ocular surface quality with standard clinical dyes to confirm the health of your eye's surface. There is no stinging sensation when the dyes are applied.
8. Evaluation of ocular surface inflammation using the clinical InflammaDry test in which tears, absorbed onto a tiny fleece pad from the conjunctival surface (overlying the white of the eye, well away from the sensitive cornea), are tested for an inflammatory marker (MMP-9) using an point-of-care immunoassay. This is an established clinical test, does not cause discomfort and the result is displayed within 10-minutes.
9. Impression cytology for laboratory analysis of inflammatory markers. This requires use of topical anaesthetic eye drops (standard in clinical practice) which might sting slightly (for a few seconds) on instillation, then briefly touching a small, flat and minimally invasive collection pad (called the EYEPRIM®) onto the white of your eye (which you won't feel).

WHAT HAPEPENS TO MY SAMPLES?

All samples will be labelled with a unique study identifying code only known to the investigator collecting the data. Only study investigators will have access to the identifiable data. The tear samples will be stored in a -80°C freezer at the Department of Ophthalmology at the University of Auckland prior to processing and will be used to determine the levels of the inflammatory markers in the tears. The conjunctival samples will be collected from the white part of your eye for determining inflammatory markers and will be immediately processed for laboratory analysis. All samples will be immediately discarded after analysis and will not be used for future analysis. They will only be used for the specified research.

If you wish to withdraw the samples at any time during or after the study, feel free to say so with no reason required.

You may hold beliefs about a sacred and shared value of any tissue samples removed. The cultural issues associated with storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There are several benefits to you from participating in this study. You will get a thorough examination of your eyes. The overall benefit is to improve quality of life.

The risks of participating in the study are negligible. Most of the assessment and tests are typically completed as part of a routine dry eye examination. There will be use of numbing drops in this study which are routinely used in a clinical setting. These may sting briefly on instillation for 10-15 seconds until your eye surface is numb. All techniques are performed by experienced clinical investigators who are trained in the technique and trained to anticipate patient movement. However, if you move during some procedures, there is a small risk of corneal abrasion. In the unlikely event this occurs, this would be expected to be uncomfortable once the numbing drop wear off (after approximately 15 minutes) but typically resolves in 1-2 hours. Any adverse events will be managed according to standard clinical protocols. All efforts are made to ensure that the tests are carried out as safely as possible and that any risks are kept to an absolute minimum.

There is a very low risk of allergic reaction (itching, redness, burning or mucous discharge) to the fluorescein, lissamine green or numbing eye drop in this evaluation. This will be extremely rare, but if it's experienced, this could last up to 12 hours.

WHO PAYS FOR THE STUDY?

The study is partially funded by The Health Research Council of New Zealand (HRC) and Maurice and Phyllis Paykel trust. The study participants will not incur any costs. All the participants will be reimbursed for their carparking costs.

WHAT IF SOMETHING GOES WRONG?

In the very unlikely event that you are injured as a result of participating in this study, you will be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the investigators will record information about you and your study participation. This includes the results of any clinical assessment data. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

<u>De-identified (special-coded) information</u>

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the investigators or any study information sent to the sponsor. Instead, you will be identified by a code. The investigators will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Only investigators in this study will have access to your coded information.

The results of this study may be published or presented, but you will not be identifiable.

Future Research Using Your Information

Following completion of this study, all links to your identity will be destroyed. Your coded information may be used for comparison to future research data sets for the overall benefit of patients with dry eye disease. Should this occur in the future, this data will no longer be traceable to you.

Security and storage of your information

All electronic data will be stored using password protected login while hard copies will be kept in locked cabinets at the University of Auckland, Grafton campus. These documents will be retained for at least six years then will be destroyed by cross shredding.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing your investigator.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Ownership Rights

Intellectual property associated with the study will belong to the University of Auckland.

WHAT ARE MY RIGHTS?

Participating is entirely your choice. You do not have to take part in this study, and if you choose not to take part you will continue to receive usual treatment and care.

If you agree to participate but then change your mind, you are free to leave the study at any time, without having to give a reason. This will not affect your future/continuing care. After participation you are free to withdraw your data, if you choose. Data can be withdrawn up to one month after the date of the data collection.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The results of this study will be presented at local meetings and national and international conferences. The results will also be published in international journals. No material which could identify you personally, will be used in any reports on this study.

All records will be kept in a secure cabinet within a locked records room and will be accessed only by the investigators of this study.

Participants may request a copy of the results of this study. The complete study is designed to last two and a half years and there will be a big delay between your participation and publication of the findings. Participants will be verbally explained their own particular results.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

Thank you for your help in making this study possible. If you have any queries, or wish to know more about the research project, please contact Dr Stuti Misra or Professor Jennifer Craig or Dr Rachel Niederer or Associate Professor Ilva Rupenthal in Ophthalmology.

RESEARCH TEAM

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If you require Māori cultural support talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

Approved by the Health and Disability Ethics Committee on 05 August 2021 for three years. Reference number [21/STH/154].