Participant Information Sheet/Consent Form

Title
A Multicenter, Vehicle-controlled, Randomized Study to Evaluate the Safety, Tolerability, Systemic Pharmacokinetics, and Pharmacodynamics of AZR-MD-001 in Patients with Meibomian Gland Dysfunction (MGD) and Evaporative Dry Eye Disease (DED)

Short Title
Study Evaluating AZR-MD-001 in Patients with Meibomian Gland Dysfunction (MGD) and Evaporative Dry Eye Disease (DED)

Protocol Number
AZ201801

Study Sponsor
Azura Ophthalmics

Local Sponsor
Syneos Health New Zealand Limited
 Unit G1, 14-22 Triton Drive, Rosedale, Auckland 0632

Principal Investigator
Professor Jennifer P. Craig

Location
Ocular Surface Laboratory, Eye Clinic
Department of Ophthalmology
Faculty of Medical and Health Sciences,
The University of Auckland,
85 Park Road, Grafton, Auckland 1023

You are invited to take part in this research study because you have Meibomian gland dysfunction (MGD) with additional signs and symptoms of Dry Eye Disease (DED). The research study is testing a new drug for the treatment of MGD and the signs and symptoms of DED. The new investigational study drug is called AZR-MD-001, hereafter referred to as the "study drug".

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, what your participation would involve, what the benefits and risks to you might be, and what would 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 15 pages long, including the Consent Form. Please make sure you have read and understood all the pages.
What is the purpose of the study?

The study drug (ointment/semi-solid drug) is considered an investigational drug to treat MGD and the signs and symptoms of DED. "Investigational" means the study drug being tested is not approved by Medsafe in New Zealand to treat these conditions.

The active ingredient in the study drug is the same active ingredient in commercially available marketed anti-dandruff shampoos (i.e., Selsun Blue, Exsel, Selsum, and Seleen). In these shampoos the active ingredient is used as an anti-fungal and anti-dandruff agent. It is marketed up to a 2.5% concentration in non-prescription products.

To understand the safety and effectiveness of the treatment, each participant will be assigned to a study group. One group will use the study drug ointment whilst the other group will use an ointment without drug- effectively a “placebo/ vehicle”.

To ensure safety, the study will be using initially very low dosages, and then increasing the dosages whilst looking for improvements in effectiveness whilst also monitoring for any unwanted effects.

What will my participation in this study involve?

The first stage of the study will last approximately 15 weeks (3 and a half months) and involve up to 6 clinic visits.

The second stage of the study will last approximately 28 weeks (6.5 months) and involve up to 7 clinic visits.

You will be asked questions about your medical history and any current medications you are taking. Below is the list of tests performed over the period of the study. These will happen at most of the visits, a concise breakdown is provided in the table below.

- **Pregnancy Test**: Women who are able to have children will be asked to provide a urine sample for a pregnancy test at their first visit. To take part in this study, women who are able to have children and who are sexually active must use effective methods of avoiding pregnancy throughout the study. The study staff will discuss with you effective methods that can be used to prevent pregnancy while participating in this trial. If you are pregnant or planning to have a baby in the next year, you should not participate in this study. However, if you do become pregnant during the trial, notify your study eye care provider immediately.

- **Vital signs (pulse rate, blood pressure)**: You will be asked to rest, seated for at least 5 minutes. The study eye care provider will then count your pulse for 30 seconds. The study eye care provider will also measure your blood pressure: Blood pressure will be measured in the same arm using a pressure cuff on the arm. You will be asked to remain seated for at least 5 minutes before the measurements can be obtained. Your weight and height will also be measured.

- **Standard Patient Evaluation of Eye Dryness (SPEED), Ocular Surface Disease Index (OSDI) and Visual Analogue Scale (VAS)**: You will be asked to fill out three questionnaires that will take about 15 minutes to complete. Each one will ask questions about how your eye disease affects your daily life and your symptoms. For the VAS, you will be asked questions regarding your ocular discomfort by placing a vertical mark on a horizontal line to indicate your level of discomfort for Burning and Stinging, Itching, Foreign Body Sensation (feeling as if something is in your eye), Eye Discomfort, Eye Dryness, Photophobia (sensitivity to light), and Pain.

- **Vision Exam**: Your vision will be tested and you will be asked to read eye charts. We will try to improve your vision by adjusting the prescription in your eyeglasses by placing different lenses in front of your eyes.
• **Eye Exam:** The study eye care provider will look closely at your eyes and eyelids through a microscope (magnifying lens) to assess the health of the surface of your eyes, eye lashes, lids, and lens. The study eye care provider will then apply a small drop of dye (2 types) on the surface of your eye to evaluate effects of MGD and DED on the ocular surface.

• **Keratograph** (selected sites): Pictures of your eyes and eyelids may be taken to evaluate the tear film and the eye redness. Your identity will not be revealed in the pictures because these are close up photographs of the eye only.

• **Sodium fluorescein corneal staining, Oxford scale:** The study eye care provider will look closely at your eyes through a microscope (magnifying lens) after applying a small drop of yellow dye on the surface of your eye to evaluate effects of dry eye on the ocular surface.

• **Lissamine green conjunctival staining, Oxford scale:** The study eye care provider will look closely at your eyes through a microscope (magnifying lens) after applying a small drop of green dye on the surface of your eye to evaluate effects of dry eye on the ocular surface.

• **Meibomian gland evaluation:** The study eye care provider will look closely at your eyelids through a microscope (magnifying lens) after applying a small amount of pressure to the outside surface of the lid. This will determine if the glands in your eyelids are working properly to help produce oil that protects the front of your eye.

• **Schirmer test:** To measure the amount of tears your eyes make, the study eye care provider will place a small piece of sterile filter paper on your lower eyelid and leave it in place for 5 minutes while your eyes are closed. Then the strip of filter paper will be removed.

• **Tear break-up time (TBUT):** The study eye care provider will look closely at the very front of your eyes through a microscope (magnifying lens) after applying a small drop of yellow dye on the surface of your eye. The study eye care provider will then shine a blue light on each eye to make it easier to see when your tear film breaks down after blinking.

• **Intraocular Pressure:** Your eye pressure will be measured after placing a numbing drop on the eye so you feel no pain, as is done in most standard eye examinations.

• **Ophthalmoscopy exam:** The study eye care provider will look closely at the back of your eyes through a microscope (magnifying lens) after applying a small drop of a dilating drop on the surface of your eye. This will cause the central black part of your eye to enlarge.

• **Meibography:** The study eye care provider will look closely at your eyelids by flipping them inside out and shining a light through them. This will determine if the oil producing glands in your eyelids are present.

**Visit Information**

Before you can start the study, you will be asked to sign this consent form. You will be instructed to maintain a stable dose of any regular medication that you need to take, or any new medication initiated during the study if possible. You should communicate any changes to your medication at your next study visit. You will be reminded to contact the study site if you experience difficulties during your study participation.

You will need to stop other dry eye treatments other than the study treatment in order to obtain an accurate assessment of your disease.

Finally, you should strictly follow the visit schedule and report any changes in condition to the investigative site personnel. If you still qualify for the study and want to continue your participation in the study at the end of the Screening Visit, you will be asked to return in approximately 2 weeks for the Baseline Visit.

At this visit, if you still qualify for the study and want to continue your participation in the study, you will be asked to apply a small amount of a Vaseline ointment to your lower eyelid at the baseline visit. This will involve using your washed index finger to apply the Vaseline ointment to the lower lid of both eyes in the clinic and to blink several times to transfer a portion of the Vaseline ointment from the lower eyelid to the upper eyelid.
This is a double-masked study, which means that neither you nor the study doctor will know which drug you are taking. The study doctor can get this information quickly if he/she decides it is needed for your safety.

The drug you receive will be assigned by chance, like the flip of a coin.

Two in every three participants will receive active treatment (not placebo) but there will be random allocations of participants to two different concentrations. The remainder will receive the vehicle.

Visits, following the Screening and Baseline visit, at approximately 2 weeks, 6 weeks, 3 months, 4.5 months and 6 months (exit visit) will take place. At each visit you will be asked about new medicines or medical events.

The decision for when you can participate in another study is determined by the drug safety information gathered from the study. Typically, you can participate in another study as soon as 30 days after the last dose of drug received in the study you are enrolled in. This information is true for most drugs; however, some drugs may be present in your body longer and that may mean you may have to wait longer before entering into another study. We will always make this information available.

Costs and Reimbursements:
There will be no cost to you for taking part in this study, nor will you be paid. All study drug, tests, procedures, and visits that are part of this study are being paid for by the Sponsor and will be provided to you at no cost. The costs of standard medical care that are not part of this study will be billed to you and/or your insurance company in the usual way.

You will be reimbursed for any reasonable travel expenses associated with the research study visits, up to a maximum of $100 per visit. You will be required to provide receipts, otherwise travel by personal vehicle will be reimbursed at 39c/km.

You cannot be in this study if you:
- Are participating in another research study currently.
- Have been in any other research study in the last 30 days.
- Have punctal plugs (small device inserted into the tear duct of the eye) or plan to have punctal plugs inserted during the study.
- Have had lid-heating therapy, meibomian gland probing, or therapeutic gland expression in either eye within 6 months prior to the screening visit.
- Have not discontinued or are not willing to remain off topical cyclosporine or integrins during the study starting 3 months before screening.
- Have not discontinued and are not willing to remain off corticosteroids or mast cell stabilisers during the study starting 2 weeks before screening.
- Have not discontinued and are not willing to remain off antihistamines (administered by any route) during the study starting 1 month before screening.
- Have not discontinued or are not willing to remain off all MGD treatments (e.g., at-home warm compress therapy, eyelid hygiene, eyelid massage, and manual lid expression) starting at least 2 weeks before screening.
- Have not discontinued and are not willing to remain off all other ophthalmic preparations including artificial tears during the study starting 72 hours before screening.
- Have not discontinued and are not willing to remain off anti-dandruff shampoos.
- Have not discontinued and are not willing to stop the use of contact lens during the study.
- Have not discontinued and are not willing to stop the application of makeup around the eye or tattooing of the lids during the study.
Table 1 below is a schedule of all the assessment and tests required for participating in this study.

### Schedule of Assessments

<table>
<thead>
<tr>
<th>Test Performed</th>
<th>Qualification Period</th>
<th>Double Masked Period (Months 4.5 &amp; 6 Stage two only)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Screening (Day -14)</td>
<td>Baseline (Day 0)</td>
</tr>
<tr>
<td>Demographics, Height &amp; Weight, Medication History &amp; Washout; Review of Concomitant Medication</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Medical &amp; Ophthalmic History</td>
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<td>✓</td>
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<tr>
<td>Pregnancy Test (for female participants)</td>
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<td>✓</td>
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<tr>
<td>Vital signs (pulse rate, blood pressure)</td>
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<td>✓</td>
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<tr>
<td>Standard Patient Evaluation of Eye Dryness (SPEED)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Ocular Surface Disease Index (OSDI)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Visual Analog Scale (VAS)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Vision Exam</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Slit-lamp biomicroscopy</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Keratograph (only at selected sites)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sodium fluorescein corneal staining, Oxford scale</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lissamine green conjunctival staining, Oxford scale</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Meibomian Gland Evaluation</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Schirmer test</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Tear break-up time (TBUT)</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Intraocular Pressure</td>
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<tr>
<td>Ophthalmoscopy exam</td>
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<td>✓</td>
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<tr>
<td>Meibography</td>
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<td>✓</td>
</tr>
<tr>
<td>Study Medication Dispensing and Return</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**What do I have to do?**

If you choose to participate in this study, you are responsible for the following:

- Be willing and able to follow the study directions and procedures given by the study eye care provider or study staff.
- Tell the truth about your medical history and medications you might be taking.
- Tell the study eye care provider or study staff about any side effects or problems you have during the study.
- Ask questions when you think of them.
- Discontinue all treatments for MGD, DED and anti-dandruff shampoos.
- Tell the study eye care provider or the study staff if you change your mind about staying in the study
  - If you decide to leave the study, you must contact the study eye care provider.
  - You will be asked to return for a final (Month 6) Exit Visit for your safety and to make sure that you are in your usual state of health.

It is important that you are honest with the study eye care provider about your health history in order to protect your safety while participating in this study.
Other relevant information about the research study
210 patients are expected to be in this study across 12 to 20 sites in New Zealand and Australia.

Do I have to take part in this research study?
Participation in any research study is voluntary. If you do not wish 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 do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

If you leave the study before completing all study visits, no more information about you will be collected. However, all the information collected before you left the study will still be used and will be stored in the study database and cannot be removed.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with The University of Auckland.

What are the alternatives to participation?
You do not have to take part in this research study to receive treatment for meibomian gland dysfunction and dry eye disease. Other options are available; which include:

- Treatment options for MGD include eyelid hygiene (e.g., lid washing and use of preservative-free artificial tears), omega-3 dietary supplementation (e.g., eicosapentaenoic acid and docosahexaenoic acid), topical antibiotics (e.g., bacitracin and erythromycin), topical corticosteroids, topical cyclosporine, oral antibiotics (e.g., doxycycline, minocycline, and tetracycline), oral omega-6 fatty acids (e.g., linoleic acid and gamma-linolenic acid), as well as unclogging of glands that are blocked, which can be achieved by applying warm compresses to the eyelid or gentle lid massaging. You do not need to take part in this research study to have MGD treated.
- Treatment options for DED include artificial tears, anti-inflammatories/immunomodulatory agents such as steroids and modifications to your eye environment such as wearing goggles. You do not need to take part in this research study to have DED treated.

What are the possible benefits of taking part?
You may or may not directly benefit medically from taking part in this study. You may gain information about your health from the different tests (e.g. laboratory tests, eye exams, etc.) that are performed during the study. It is possible that if you have MGD and/or DED it may get better, stay the same, or get worse. Information from this study may help the Sponsor and doctors learn about the study drug that could help others with MGD and/or DED.

What are the possible risks and disadvantages of taking part?

Possible Risks and Side Effects of AZR-MD-001
Medical treatments often cause side effects. You may have none, some or all of the effects mentioned below, and they may be mild, moderate or severe.

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

As the study drug is investigational, all of its side effects may not be known.
You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in the study.

Over 300 patients have been dosed with the active ingredient in the study drug as a treatment for the same or related ocular conditions.

Adverse events reported following topical ocular use of products containing the active ingredient include the following:

- superficial punctate keratitis (cell death on the surface of the cornea causing eye discomfort and slight vision impairment)
- conjunctivitis (damage to the cells that cover the front of the eye)
- eye pain
- lid swelling
- eye redness which resolved upon stopping the treatment.

**Risks from Study Procedures:**

Fluorescein and lissamine dye eye drops are safe, but rarely cause an allergic reaction. Side effects from their use on the eye include the following:

- redness
- watering
- itchiness
- eye discoloration
- irritation of the eye
- swelling of the eyelids

These side effects usually go away in about an hour after the drops are put on the eye. These side effects are rare.

The intraocular pressure exam may cause irritation to the surface of the eye or blurred vision. Very rarely people report experiencing blurred vision and eye discomfort for up to 24 hours after this exam has been performed. Also, there is a risk of allergic reaction (itching, redness, burning, or mucous discharge) to the ingredients of the anaesthetic drop used in this evaluation. If experienced, this could last up to 12 hours.

The gland expression exam may cause eye discomfort. Some people report experiencing eyelid pain and eye discomfort after this exam has been performed.

If you become injured during the study, you should inform the treating doctor or nurse that you are participating in a research study.

**Risks of Pregnancy and Breast Feeding:**

**Reproductive Risks for Women of Child-Bearing Potential**

If you are a sexually active woman of child-bearing potential it is very important that you do not become pregnant whilst taking the study drug during this study.

A woman of child-bearing potential is any pre-menopausal woman who may become pregnant. If you are unsure if this applies to you, please check with the study doctor before you start the study treatment.

There may be risks to you and/or your child/unborn child that are not known at this time and so women of child-bearing potential must use one of the following methods of birth control, while you are in the study. Highly effective methods of birth control (contraception) are those with a failure
rate of less than 1% (less than one pregnancy per 100 women using method for one year) and include:

- Implant contraceptive (e.g. Jadelle)
- Intra-uterine device (IUD) containing either copper or levonorgestrel (e.g. Mirena)
- Male sterilization (vasectomy)
- Female sterilization (e.g. by bilateral tubal ligation (‘tying tubes’) or hysterectomy)
- Total abstinence from heterosexual intercourse during the entire period of risk associated with the study drug, if this is in line with your preferred and usual lifestyle

Other methods for which the failure rate is between 5% and 10% in real life use include:

- Injectable contraceptive (e.g. Depo Provera)
- Oral Contraceptive Pill (combined hormonal pill or progestogen-only ‘mini-pill’)
- Vaginal contraceptive ring (e.g. NuvaRing)

If you are unsure which method of birth control you are using (or want to start using) and whether it is acceptable for this study, please ask the study doctor for more information.

If you do become pregnant during the study, you must tell the study doctor as soon as possible. Your study eye care provider and study doctor may ask you questions about your pregnancy and your baby, and you will be contacted for information about your pregnancy periodically.

**Unforeseen Risks:**

There may be additional risks to you while being in this study that are not known at this time. If you experience any unusual side effects, please contact your study doctor immediately.

Please ask your study doctor any questions you may have about the study risks.

**Possible risks and side effects to stopping existing medication:**

It is possible that you may experience side effects if you stop taking existing medication and/or are exposed to vehicle/placebo. There is also a possibility that your symptoms may return and be problematic. We recommend that you consult with your GP to learn about these potential side effects. Please ask the study doctor or study staff to explain these terms to you if you do not understand what any of these side effects mean.

**What will happen to my test samples?**

As part of this study, pictures of your eyes and eyelids will be taken. If you and your study site are selected to provide the photographs taken of your eyes and eyelids, you will be asked to decide whether you provide the sponsor the right to use, copy and give out the pictures for research, advertising or in scientific journals or magazines. Your pictures may be used as part of a larger presentation. Your pictures may also be edited.

Azura Ophthalmics may give other people or companies permission to use your pictures. The sponsor will hide your identity. Your name or any other information that can identify you will not be on the pictures and you have the right to review your pictures and cancel their release at any time. A tick box on the consent page will require completion if you and your site are selected to participate. If you choose or choose not to provide your pictures, your decision will not affect your study participation in any way.
What if new information arises during this research study?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your study eye care provider will tell you about it in a timely manner and discuss with you whether you want to continue in the research study. If you decide to withdraw, your study eye care provider will make arrangements for your regular health care to continue. If you decide to continue in the research study you will be asked to sign an updated consent form.

Also, on receiving new information, your study eye care provider or study doctor might consider it to be in your best interest to withdraw you from the research study. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

Can I have other treatments during this research study?

Whilst you are participating in this research study, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study eye care provider and study doctor about any changes to these during your participation in the research study. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research study.

What if I withdraw from this research study?

If you decide to withdraw your consent during the research study, the study eye care provider, study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research study results. If you do not want them to do this, you must tell them before you join the research study.

If you leave the study or if you are taken out of the study, you will be asked to return for a final visit to have some end-of-study evaluations or tests.

Could this research study be stopped unexpectedly?

The Sponsor, study eye care provider or study doctor can decide to stop the study at any time. The study eye care provider, study doctor, the Sponsor or its representatives, Ethics Committees, or regulatory agencies may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study eye care provider or study doctor’s instructions.
- If we find out you should not be in the study.
- If the study is stopped.
- If it becomes harmful to your health.
- If you become pregnant (females).
- If the drug is shown not to be effective.
- The drug is shown to work and not need further testing.

What happens when the research study ends?

The study drug will not be available for use outside of the study or when the study ends.

Information obtained from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you. After you exit the study your study doctor will discuss treatment options available to you and their important potential benefits and risks.
What will happen to information about me?

By signing the consent form you consent to the study eye care provider and relevant research staff collecting and using personal information about you for the research study. Any information obtained in connection with this research study that can identify you will remain confidential.

All information collected during the study will be coded with the unique study identification number assigned to you when you are enrolled. The study eye care provider is responsible for keeping the code list that makes it possible to link your code to your name. This will be kept in a safe place to ensure that if needed you can be identified and contacted. The code list and your study data will be retained for at least 15 years after the end of the research study.

Your information will only be used for the purpose of this research study and it will only be disclosed with your permission, except as required by law.

Your personal health information obtained during this research study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the sponsor, the institution relevant to this Participant Information Sheet, The University of Auckland or as required by law. These authorised users will receive full access to your original personal health information, which may or may not include your name. It is possible that your personal health information can be traced back to you even if it does not include your name. Therefore, complete privacy of your health information may not be possible. By signing this consent form, you are giving your study eye care provider permission to share your personal health information with all authorised users.

The following people will have access to your study records:

- The study eye care provider and study doctor
- Sponsor company or research institution
- Monitor(s) and other auditors(s) who assure the study is conducted properly
- Medsafe in New Zealand
- Other country, state or federal regulatory agencies
- The Health and Disability Ethics Committee (HDEC) that reviewed and approved this study

Some of the organisations that will have your data will be located outside of New Zealand, including in countries where data protection requirements may be different or less restrictive than in New Zealand. However, Azura Ophthalmics will take reasonable measures to keep your personal health information confidential. Absolute confidentiality cannot be guaranteed. By signing this document, you agree to the transfer of your personal health information.

Information obtained from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

A description of this clinical study may be available on www.ClinicalTrials.gov as required by Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In accordance with New Zealand privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.
Your GP and/or relevant specialist may be informed of your participation in this study and by signing and dating the Participant Consent Form, you will also be giving permission for information regarding your medical history or your ongoing medical condition to be obtained from your GP and/or relevant specialist.

If you are admitted to another hospital during the course of; or arising out of, your participation in the study, you give permission for the release of any relevant records from that hospital. This would include records relating to a stay in the hospital and may include such information as test results, medications you were given during your stay and the reason why you were hospitalised.

**What if something goes wrong?**

If you suffer any injuries or complications as a result of this research study, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

As this research study is for the principal benefit of its commercial sponsor Azura Ophthalmics Pty Ltd., if you are injured as a result of taking part in this study you won’t be eligible for compensation from ACC. However, Azura Ophthalmics Pty Ltd. has satisfied the Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand’s ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own, they are not legally enforceable, and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
  - The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the investigators, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you.
- An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

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.
Who pays for the study?

This research study is being conducted by Azura Ophthalmics Pty Ltd. Azura Ophthalmics is paying The University of Auckland for undertaking this research study. Syneos Health New Zealand Limited is conducting the study in New Zealand on behalf of Azura Ophthalmics and is therefore considered the local New Zealand sponsor.

Azura Ophthalmics may benefit financially from this research study if, for example, the study assists Azura Ophthalmics to obtain approval for a new drug.

You will not benefit financially from your involvement in this research study even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Azura Ophthalmics.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Azura Ophthalmics, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

The University of Auckland will receive a payment from Azura Ophthalmics for undertaking this research study.

No member of the research team will receive a personal financial benefit from your involvement in this research study (other than their ordinary wages).

Who has reviewed the research study?

All research in New Zealand involving humans is reviewed by an independent group of people called the Health and Disability Ethics Committee (HDEC). The ethical aspects of this research study have been approved by Southern Health and Disability Ethics Committee.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Professor Jennifer P Craig, Principal Investigator
Phone: 021 853 664
Email: jp.craig@auckland.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

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 or emailing hkw@adhb.govt.nz.
You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz
Consent Form

I have read, or have had read to me, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the research staff collecting and processing my information, including information about my health.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study. Yes ☐ No ☐

PHOTO RELEASE (FOR KERATOGRAPH)

I provide permission to the sponsor to use, copy and give out the pictures taken of my eyes and eyelids for research, advertising or in scientific journals, magazines or large presentations.

I do not provide permission to the sponsor to use, copy and give out the pictures taken of my eyes and eyelids for research, advertising or in scientific journals, magazines or large presentations.

Declaration by participant:
I hereby consent to take part in this study.

Participant’s name: __________________________

Signature: __________________________ Date: ____________

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name: __________________________

Signature: __________________________ Date: ____________