RESEARCH SUBJECT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Vance Thompson Vision / "A single center randomized controlled, two arm investigator initiated study to assess the efficacy of Kera Sol Tears on surgical temporary ocular discomfort syndrome (STODS) in subjects following LASIK."**
Protocol Number:	**Pro00087420**
Principal Investigator: (Study Doctor)	**Daniel Terveen, MD**
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Introduction:

What is a Research Study?

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this study?

- Someone will explain this study to you.
- This form sums up that explanation.
- Taking part in this study is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand something, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this study?

We expect that your taking part in this study will last up to 3 months, starting with the day of your initial evaluation, and for 2 weeks after your scheduled procedure.

Purpose of the Study?

The purpose of this study is to assess the impact of Kera Sol artificial tears on the signs and symptoms of Surgical Temporary Ocular Discomfort Syndrome (STODS).

After any eye surgery, it can be common for your eyes to feel dry and uncomfortable for a short time. This happens because the procedure can temporarily disrupt the normal tear production or nerve function on the eye's surface, and we anticipate it will get better as you heal.

About 60 subjects will take part in this study.

What happens to me if I agree to take part in this study?

If you decide to take part in this study, on the day of your procedure you will be randomized (like the flip of a coin) to one of two groups: You cannot choose your study group.

Group 1: If you are randomized to Group 1, you will receive standard prescribed post-operative eye drops and regimen. This includes a combination steroid and antibiotic drop dosed four times daily for the first week and twice daily for the second week.

Group 2: If you are randomized to Group 2, you will receive standard prescribed post-operative eye drops and regimen. This includes a combination steroid and antibiotic drop dosed four times daily for the first week and twice daily for the second week. You will also receive Kera Sol artificial tears dosed four times daily for two weeks.

Both groups will be followed for 14 days (2 weeks) after your Laser In Situ Keratomileusis (LASIK) procedure. Throughout the study, you will be asked to:

- Complete daily logs of your eye drop usage
- Report your dry eye symptoms using a standardized questionnaire.

- Eye health measurements will be performed at each of your follow-up visits (1 day, 1 week, and 2 weeks post-surgery):
  - Visual acuity (tests to assesses how clearly someone can see objects at a certain distance)
  - Slit lamp biomicroscopy (detailed eye examination that uses a microscope combined with a bright light)
  - Corneal fluorescein staining (a test that uses a special dye [fluorescein] and a blue light to examine the surface of the cornea) to assess dryness
  - Low contrast visual acuity (a test that evaluates how well you can see objects when there is reduced contrast between the object and its background)
  - Intraocular pressure measurement (measures the pressure inside the eye)
  - Manifest refraction (an eye exam that measures a person's prescription for eyeglasses or contact lenses)

Could being in this study hurt me?

The risks or discomforts that you may expect from taking part in this study include:

- Ocular discomfort
- Ocular itching
- Light sensitivity
- Foreign body sensation (a feeling that something is in the eye)
- Burning and stinging
- Eye redness
- Allergic reaction

These are similar side effects you may experience following your LASIK surgery if you choose not to participate in the study. These are different risks than those parts of the LASIK procedure you have elected to undergo. The LASIK procedure is not part of this study.

While the study procedures are generally safe, there may be some risks associated with participation. If you feel you experience any adverse effects (side effects), please inform the study staff immediately.

There may be other risks that are unknown.

Will being in this study benefit me?

There may be no direct benefit to you from participating in this study. However, you may experience improved eye comfort following your surgery. Information learned from the study may help other people in the future.

Will I be paid for taking part in this study?

For taking part in this study, you will be paid $50 for each completed visit, for up to a total of $250. It will be paid in the form of a check at the end of the study. You will only be paid for completed visits. A check will be mailed to your current address 2-4 weeks after your last visit.

If you have any questions regarding your compensation for participation, please contact the study staff.

Are there additional costs to being in the study?

There are no additional costs to you for being in the study. You or your insurance company will still be responsible for the costs of your LASIK surgery and needed follow-up visits once you exit the study.

What other choices do I have besides taking part in this study?

You do not have to be this study to receive treatment. Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

What happens to the information collected for this study?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this study, including:

- The study sponsor
- People who work with the study sponsor
- Government agencies, such as the Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this study

We may publish the results of this study. However, we will keep your name and other identifying information confidential.

We will protect your information from disclosure to others to the extent required by law. We cannot promise complete confidentiality.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Compensation for Injury

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor’s or study site’s decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00087420.

Can I be removed from this study without my approval?

The study doctor can remove you from this study without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the study
- You need a treatment not allowed in this study
- You become pregnant
- You are unable to take the study drug
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your choice to stay in this study.

What happens if I agree to be in this study, but I change my mind later?

Your participation in this study is voluntary. You may choose not to participate or to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Agreement to be in the Study

This consent document contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent document, please ask the person explaining this document or one of the study staff.

By consenting to participate you agree that you have been given a copy of all pages of this signed and dated consent document. You have had an opportunity to ask questions and received satisfactory answers to all your questions about this study. You understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care. You understand that your study-related medical records may be reviewed by the company sponsoring the study and by government authorities.

Statement of Consent
IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE, YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.

Your signature documents your consent to take part in this study.

Signature of Subject	Date
Printed name of Subject	
Signature of person explaining and obtaining consent	Date
Printed name of person explaining and obtaining the consent	

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include

- Representatives of Vance Thompson Vision.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ _____

Signature of Subject Date

_____

Printed name of Subject