PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Performance of Avaira Vitality Toric (Fanfilcon A toric) after at least One Month wearing Avaira Toric (Enfilcon A toric) [redacted]

PROTOCOL NO: EX-MKTG-67

STUDY DOCTOR: [redacted]

STUDY SITE: [redacted]

TELEPHONE: [redacted]

SPONSOR: CooperVision, Inc.

You are being asked to take part in a research study involving the wearing of contact lenses on a monthly schedule. Before you decide it is important for you to read about why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask the study doctor or study staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate if participants who wear Enfilcon A toric (Avaira toric) lenses can be refit into Fanfilcon A toric (Avaira Vitality toric) lenses and successfully wear them for at least one month of daily wear. Successful wear will be assessed by the lens performance and how well the lenses fit. In addition to lens wear experience, visual acuity, vision quality, handling, comfort, dryness, and eye health will be measured.

Approximately 48 men and women between 18 and 40 years old are expected to be dispensed lenses in this two month study at 4 sites across North America.

WHY HAVE I BEEN CHOSEN?

The participants involved in this study will be selected on the basis of having healthy eyes, except for the need for vision correction and currently wearing soft toric lenses. Additional criteria are listed below.

<u>You may be included in the study if</u>

- You are between 18 and 40 years of age (inclusive)

- You had an eye exam in the last two years
- You currently wear soft toric lenses
- You can be successfully fit with study lenses
- You have astigmatism of at least 0.75D in each eye
- You have a contact lens prescription that fits within available parameters of the study lenses
- You have good vision in each eye with spectacles and the study lenses
- You have healthy eyes
- You are willing to follow the lens wear schedule (at least 5 days per week, more than 8 hours/day, assuming there are no reasons for not doing so) and the study visit schedule

<u>You may NOT be included in the study if</u>

- You have a history of not achieving comfortable lens wear (5 days per week; more than 8 hours/day)
- You have eye abnormalities that may impact the study outcome
- You have eye or health conditions or currently take medications that may impact the study outcome
- You had certain eye surgeries in the past
- You depend on spectacles for near work over the contact lenses (presbyopia)
- You had previous refractive surgery: PRK, LASIK, LASEK, CK, ICL or any other surgery to correct the power of your eyes and attempt to eliminate the need for a glasses correction
- You are currently participating in any other type of eye related clinical research study
- You use rewetting/ lubricating eye drops more than once per day

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you decide to take part you will be asked to sign the paper Consent Form once you have had the opportunity to read all of the instructions and information provided, and received satisfactory answers to any questions you may have. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

You may be asked to wear two different types of soft toric contact lenses. Enfilcon A toric (Avaira toric) contact lenses will be worn in both eyes for the first month, for a minimum of 5 days per week and 8 hours each day. During the second month you will be wearing either Enfilcon A toric (Avaira toric) contact lenses or Fanfilcon A toric (Avaira Vitality toric). Depending when the Fanfilcon A toric (Avaira Vitality toric) lenses will be available from the sponsor, you may be required to wear the Enfilcon A toric (Avaira toric) lenses for longer than 1 month. You will not know which study lens you are wearing during the second month, but the study doctor and study staff will have this information. Both of these contact lenses have been approved by the U.S. Food and Drug Administration (FDA) for sale in the United States.

There will be up to 5 study visits and your participation will last for at least 2 months.

Visit 1 (Screening)

At the initial visit, your eligibility for the study will be assessed and your optimum prescription with the study lenses will be established. The following procedures will take place:

- You will be asked to read and sign this Participant Informed Consent Form before any study-related procedures take place
- You will be asked about your health and medication history
- You will be asked about your contact lens wearing history
- Your vision will be checked
- Your eyes will be checked. This will be done by the use of a bright light for short periods of time, a procedure to highlight the tear film and front surface of the eye using an orange solution (fluorescein), and a baseline assessment of the front part of your eye.

If you are already wearing lenses with optimum prescription, then you will be issued Opti-free PureMoist multipurpose solution and asked to return for a baseline visit after at least 29 days.

Visit 2 (Lens Fitting – If Necessary)

If you require a new or modified pair of study lenses, then you will be asked to return to get lenses in your prescription. At this visit, the new or modified study lenses will be assessed on your eyes, and, if you are still eligible, a pair of lenses and Opti-free PureMoist multipurpose solution will be given to you. You will be asked to return for a baseline visit wearing these lenses after at least 29 days. You should wear the lenses for a minimum of 2 hours before the study visit. If you come to the visit without lenses or with less than 2 hours of lens wear on that day and you are not having any problems with the lenses, the visit should be rescheduled.

Visit 3 (Study Lens Fitting)

You should come to this visit having worn the study lenses for at least 2 hours. At this visit, the following will take place:

- You will be asked about any changes in your health or the medications you take.
- Your vision will be checked.
- The fit of the study lenses will be checked.
- Your eye health will be checked.
- You will be asked in a questionnaire how you feel about wearing the study contact lenses.
- Your eyes will be examined after removal of the contact lenses.

After your eyes are examined, a second study lens pair will be inserted into your eyes. The study doctor will perform assessments to determine the fit of the new study lenses. If you are still eligible, this new pair of study lenses will be issued to you.

You will be asked to return for a two-week (14 ± 2 days) follow-up visit wearing your second pair of study lenses. You should wear the lenses for a minimum of 2 hours prior to the appointment.

If you attend without lenses or with less than 2 hours of lens wear on that day and you are not having any problems with the lenses, the visit should be rescheduled.

Visit 4 (2-Week Follow-Up)

At this visit, the following will take place:

- You will be asked about any changes in your health or the medications you take.
- Your vision will be checked.
- The fit of the study lenses will be checked.
- Your eye health will be checked.
- You will be asked in a questionnaire how you feel about wearing the study contact lenses.
- Your eyes will be examined after removal of the contact lenses.

You will be asked to return for a one-month follow-up visit (28 ± 3 days from the dispensing date of your second pair of study lenses). Once again you should wear the lenses for a minimum of 2 hours prior to the appointment. If you attend without lenses or with less than 2 hours of lens wear on that day and you are not having any problems with the lenses, the visit should be rescheduled.

Visit 5 (One-Month Follow-Up)

At this visit, the following will take place:

- You will be asked about any changes in your health or the medications you take.
- Your vision will be checked.
- The fit of the study lenses will be checked.
- Your eye health will be checked.
- You will be asked in a questionnaire how you feel about wearing the study contact lenses.
- Your eyes will be examined after removal of the contact lenses.

At the end of this study visit you will be exited from the study.

Study appointments are important in order to collect data about the study lenses and to ensure continued eye health; therefore you must follow the appointment schedule as instructed by the study doctor. Each study visit will take approximately 1 hour to complete.

You will be provided with a lens care system to use during the study by the study doctor.

WHAT DO I HAVE TO DO?

You will be required to follow the directions given to you by the study doctor. You are required to follow the follow-up visit schedule and provide reasonable notice if you cannot attend an appointment. During the study you will be removing your contact lenses every day, and you will not be allowed to sleep in the study lenses. **If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems, you must immediately**

remove your contact lenses and contact the study doctor immediately. Unscheduled visits will be made available to you at your request, or if the study doctor thinks it is in your best interest. Since swimming has been associated with problems connected to continuous wear lenses (such as Microbial Keratitis, which is an infection of the cornea) you should remove your lenses while swimming.

WHAT ARE THE POSSIBLE SIDE EFFECTS, DISADVANTAGES, AND RISKS OF TAKING PART?

Side effects that may occur during the wearing of contact lenses include:

- discomfort
- dryness
- aching or itching eyes
- excessive watering of the eyes
- unusual eye secretions
- redness of the eye
- variable or blurred vision
- rainbows or halos around objects
- dry eyes

More serious risks may include sensitivity to light, inflammation of the color part of your eye, swelling in the cornea or eye infection. Although contact lens-related infections are very infrequent, the possibility does exist. The incidence of infection due to daily wear soft lenses is 0.035%. Almost always an infection will occur only in one eye. This risk is assumed by 35-million Americans who currently wear contact lenses.

You must remove your lenses immediately if a problem occurs. You must immediately contact the study doctor if you notice any pain, discomfort, redness, blurring of vision, or any other possible side effects. The study visits do not replace your regular periodic eye examinations.

If you are unable to reach your study doctor, please remove your lenses and go to your nearest hospital emergency room. Inform the attending staff of your participation in the study.

If a complication should occur during the study your eye may be photographed, a longer appointment may be necessary, and you may be referred for medical treatment. You may be required to wear spectacles for a period of time.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The expected benefits of contact lens wear include improved vision, comfort, convenience, and cosmetic advantage. You may experience these benefits from participating in this study, although this cannot be guaranteed. The information obtained from this study may help us to develop better contact lenses and contact lens materials.

WHAT ARE MY ALTERNATIVES TO TAKING PART?

You do not have to take part in this study to correct your eyesight. Other vision correction alternatives are available to you outside of the study through your eye care practitioner.

WILL THERE BE ANY COSTS TO ME?

There is no cost to you, your private medical insurance (if any), or the public health insurance plan for study procedures. Study contact lenses and care products will be provided at no charge for the duration of the study.

WILL I BE COMPENSATED?

If you complete all study visits you will receive up to a total of $200.00. If you withdraw from the study before it is completed, you will receive $40.00 for each completed visit. A completed visit means all scheduled study procedures have been carried out.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the product that is being studied. If this happens, your study doctor will tell you about it as soon as possible and discuss with you whether you wish to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your eye care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your study doctor might consider it to be in your best interests to withdraw you from the study. The study doctor will explain the reasons and arrange for your eye care to continue.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the sponsor decides to stop the study early, the reasons will be explained to you. After the study, whether you successfully complete the study or are discontinued from the study, the study doctor will be able to advise you of appropriate contact lens products for you. The sponsor may decide to stop the study if new product safety information becomes available that indicates it would be necessary to stop the study. If participants participating in this study experience an unexpected number of side effects the study would be stopped.

WHAT IF SOMETHING GOES WRONG?

Should you require medical treatment as a result of your participation in this study, you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by your private medical insurance (if any). Neither your eye care provider nor the sponsor will automatically provide any other compensation to you. However, by signing this consent form, you do not give up any of your legal rights, including your right to claim compensation for injury where you can prove negligence.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

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.

All information that is collected about you during the course of the study will be kept strictly confidential, except where release of information is required by law.

The sponsor, the sponsor's representative (i.e. CooperVision), the health authorities (e.g. FDA) or Sterling Institutional Review Board (an independent committee that reviews the ethical aspects of some studies to help protect the rights and welfare of study participants), may inspect the detailed study records (to ensure accuracy of the data) kept by the research clinic, which may contain your name. Inspection of the files will be conducted by an appropriately qualified person, and your identity will only be traceable at the site of the study. Any information about you which leaves the clinic will have your name and address removed so that you cannot be recognized from it.

If you experience a study related health problem, this may be reported to Sterling Institutional Review Board and the sponsor.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy. You have a right to check your health records and request changes if the information is not correct.

Your family doctor may be told about your taking part in this study, unless you do not give permission.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results of the study may be published or sent to the appropriate health authorities in any country in which the products may ultimately be marketed, but your name will not be disclosed in these documents.

AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

Under the privacy laws, you have the rights to decide who can use your protected health information (called PHI). When you sign this form, you are saying that you will allow the use of your protected health information for this study.

The information that will be collected about you as a part of this research includes:

- Name
- Address
- Telephone number

- Birth date
- Race
- Sex
- Family medical history
- Allergies
- Medications you take (current and past)
- Results of study tests and study procedures
- Other information from other doctors' offices, clinics, and/or hospitals that is needed for the study

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- The study sponsor (or sponsor representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Sterling Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)
- Other government agencies in other countries
- Other doctors, health care professionals or research staff who are involved in the study

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

This permission (also called an authorization) will have no end date.

You may also take away (or withdraw) your permission for the use of your protected health information at any time. If you choose to withdraw your permission, you must tell your study doctor.

The study doctor's mailing address is [redacted]. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

WHO IS ORGANIZING AND FUNDING THE RESEARCH?

A major contact lens manufacturer (CooperVision) is sponsoring this study. The sponsor will pay the study doctor and participants for their time, effort, and expense to conduct this study.

FOR FURTHER INFORMATION

If you have any questions, concerns or complaints about this research project, or if you experience a research-related injury, please contact [redacted] or the study staff at [redacted] or [redacted]

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

Participation in this study is voluntary; if you decide not to participate there will be no penalty or loss of benefits to which you were otherwise entitled. You may discontinue participation in this study at any time without penalty or loss of benefits to which you were otherwise entitled.

You will be given a copy of this Participant Informed Consent Form, which has 10 pages, to keep.

CONSENT FORM

Please Initial Box

1. I confirm that I have read the informed consent for the above study and have had the opportunity to ask questions. Any questions I had were answered to my satisfaction. ☐

2. My participation is voluntary and I am free to withdraw at any time, without giving any reason, without my future care or legal rights being affected. ☐

3. I am aware that sections of any of my clinic notes may be looked at by responsible individuals from the sponsor company or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

The investigator has my permission to tell my regular doctor about my being in this study:
YES ☐ NO ☐

Name of Participant / Participant ID	Signature	Date
Name of Person taking Consent (if different from Study Doctor)	Signature	Date
Study Doctor	Signature	Date

Study Doctor Address	City	State	Zip

Office Number	Emergency Phone Number