PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: CLINICAL EVALUATION OF BIOFINITY CONTACT LENSES

PROTOCOL NO: CV-23-28

STUDY DOCTOR: Jennifer S Fogt, OD MS

STUDY SITE: The Ohio State University College of Optometry
338 West 10th Avenue
Columbus, OH 43210

TELEPHONE: 614-292-8858
614-292-0882 (emergency only - 24 hours)

SPONSOR: COOPERVISION INTL LTD

You are being asked to participate in a clinical research study. This clinical research study is a study of a new device in a small number of participants. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The study doctor or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. This form may contain words that you do not understand. Please ask the study doctor or study staff to explain the words or information that you do not understand. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

NATURE AND PURPOSE OF THE STUDY

This is a clinical research study of contact lenses. The purpose of this study is to confirm that the clinical performance of the Test Lenses is similar to the Control Lenses. The risks associated with participation in this clinical research study should be minimal.

This research study will evaluate the clinical performance of investigational silicone hydrogel lenses that have a slight modification to how they are made (Test Lenses) compared to currently marketed contact lenses (Control Lenses). While the control contact lenses designs are cleared by the United States Food and Drug Administration (FDA) for commercial distribution, the investigational contact lenses (Test Lenses) are not approved for sale by the FDA.

DURATION

This study will be a dispensing study, which means that lenses will be given to you for wear away from the study clinic.

Your participation in this study will last up to two (2) weeks and will involve at least 8 hours of lens wear per day and 5 days per week. The specific wear period and study visit requirements will be verbally detailed along with a subject instruction guide.

ELIGIBILITY CRITERIA

Up to 114 people, age 18 and older, will participate in this study. Before being enrolled in this study, you must meet the eligibility criteria. The study doctor will ask questions and examine your eyes in order to determine your eligibility:

Inclusion criteria

You will be eligible to participate in the study if you:

- Have had a self-reported eye and vision examination in the last two years.
- Are at least 18 years of age and have full legal capacity to volunteer.
- Have read and understand the information in this consent form.
- Are willing and able to follow instructions and maintain the appointment schedule.
- Meet the vision requirements of the study.
- Currently wear daily wear soft contact lenses and use a peroxide or multipurpose cleaning solution and disinfecting regimen (solution must be from the approved list).
- Have clear corneas and no active ocular disease.
- Have not worn lenses for at least 12 hours before the initial study examination.
- Are willing to wear the study contact lenses for at least 8 hours a day, 5 days a week.

Exclusion criteria

You will be excluded from the study if you:

- Have never worn contact lenses before.
- Are currently wearing daily disposable contact lenses.
- Have any systemic disease affecting ocular health.
- Are using any systemic or topical medications that will affect ocular health.
- Have any ocular disease or abnormality that would affect the wearing of contact lenses.
- Have any clinically significant lid or conjunctival abnormalities, active neovascularization or any central corneal scars.
- Are aphakic (have no lens in your eye).
- Have undergone corneal refractive surgery.
- Are participating in any other type of eye related clinical or research study.

STUDY VISITS AND PROCEDURES

If you choose to participate, you may be asked to wear up to two pairs of study lenses over the course of the study. You are free to choose to participate or decline to participate at any time.

Visit 1 – Baseline

The purpose of the initial visit is to determine if you are eligible to participate in the study. Your eyes will need to be healthy in order to take part in the study. If you have had any eye problems in the past, you should inform the study doctor. You will be asked about your demographics (age, sex, race, etc.), medical and contact lens wearing history. A baseline assessment of the front part of your eye will be done prior to the fitting of any study contact lenses. The use of a bright light for short periods of time is an essential part of the examination. It may also be necessary to highlight the tear film and front surface of the eye using an orange solution (fluorescein). This is short-lasting and does not interfere with vision.

If you are eligible, you will then be fitted with a pair of study lenses. The study lenses you are fit with first will be assigned by chance, like the flip of a coin. You will wear both the Test and Control Lenses during this study but neither you nor the study doctor will know what lenses you are wearing at any time. The study doctor can find out what lenses you are wearing in the event of a medical emergency.

The study doctor will evaluate the study lens performance and fit on your eyes and adjust if needed. You will be asked to wear the lenses for at least 8 hours per day, 5 days for one week. During the week you will be asked to complete a questionnaire electronically at home using your own electronic device on two different days.

Visit 2 – 1 Week Visit

You will come to the study clinic after wearing the study lenses for at least 5 hours. Your vision wearing the study lenses will be assessed and you will be asked questions about your experience with the study lenses. The study doctor will evaluate the study lenses and their fit on your eyes. The lenses will be removed and the study doctor will assess the front of your eyes before fitting you with a second pair of study lenses.

The study doctor will evaluate the study lens performance and fit on your eyes and adjust if needed. You will be asked to wear the lenses for at least 8 hours per day, 5 days over the next week. During the week you will be asked to complete a questionnaire electronically at home using your own electronic device on two different days.

Visit 3 – 2 Week Visit

You will come to the study clinic after wearing the study lenses for at least 5 hours. Your vision wearing the study lenses will be assessed and you will be asked questions about your experience with the study lenses. The study doctor will evaluate the study lenses and their fit on your eyes. The lenses will be removed and the study doctor will assess the front of your eyes.

At the end of the study lens evaluation, your eyes will be examined to make sure they are free of any side effects and you will be exited from the study after signing the study exit form.

All tests performed during the study will be standard eye tests, similar to those performed by your eye care practitioner, and may include:

- Examination of your eye health using white light and magnification
- Placing the study contact lenses on your eyes and removing them
- Assessment of how the study contact lenses fit on your eyes and vision through an examination and/or questionnaires
- Taking pictures/video of your eyes (without using a flash). You will not be identified in any pictures or video.
- Completing surveys or questionnaires about your comfort, vision, and ability to handle the lenses

YOUR RESPONSIBILITIES

As a participant in this study you agree to:

- Keep your visit appointments.
- Inform the study doctor of any complications, discomfort, or pain.
- Tell the study doctor about any side effects, other doctor visits, or hospitalizations that you may have during and/or immediately after participation in the study.
- Tell the study doctor of any medications that you are taking.
- Tell the study doctor if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the study doctor if you change your mind about continuing in the study.
- Tell the study doctor if you are participating in any other research study at this time.
- Keep the study lenses out of the reach of children.

POTENTIAL RISKS

There are potential risks when participating in research studies involving investigational devices. The investigational contact lenses are similar to lenses that have been approved by the FDA, but are produced on a new manufacturing line. Prior to clinical testing, these investigational contact lenses have undergone safety assessments as determined by CooperVision, Inc., however not all risks associated with the use of the study lenses are currently known.

- All study lenses in this study are intended for daily wear.
- Complications that may occur during the wearing of contact lenses include discomfort, dryness, aching or itching eyes, excessive tearing, discharge, redness and variable or blurred vision. More serious risks may include light sensitivity, inflammation of the iris of the eye, swelling of the clear cover of the eye (corneal edema) or eye infection. Although contact lens-related infections are very infrequent, the possibility does exist. There has been a low incidence of infections with contact lens wearers (~0.1%). The incidence of corneal and conjunctival inflammation with contact lens wear is estimated to be low (0.01% to 0.45%). Almost always an infection will occur only in one eye.

- Investigational lenses provided by CooperVision will be required to pass appropriate quality control tests. However, there is a possibility that lens fit to the eye might be different in terms of movement and fit or lenses might bind to the eye surface. The eye response and lens fitting characteristics including lens movement will be monitored closely during the study visits by the study doctor.
- Symptoms of complications may include discomfort, dryness, burning, stinging, painful eye, excessive tearing, discharge, extreme light sensitivity, and blurred vision. If any of these or other unusual signs or symptoms occur, you should immediately seek care and report your symptoms to the study doctor using the contact information on the first page of this document. Prompt medical attention for eye infection during contact lens wear is crucial in avoiding more serious complications.

There are no anticipated risks related to any of the study procedures in this study. The examination of the eye and tear quality using light and microscope is a standard clinical procedure used at an eye doctor's office and has not been reported to cause damage to the eye.

Drops of one or more types of dye may be used to help examine the front part of your eyes during the study visits. These dyes are a type which is typically used by eye care practitioners during routine eye examinations. Some people may have an allergic reaction to the dyes. Allergic reactions to the dye are rare. Allergic reactions may appear as a rash or itching of your skin.

POTENTIAL BENEFITS

You will not personally benefit from your participation. Even if there is no personal benefit to you, information from this research will provide insight into current and future product development aimed at improving contact lens comfort.

ALTERNATIVES

Since this study is for research purposes only, your alternative is to not participate.

COSTS

There are no costs to you for taking part in this study.

COMPENSATION

If you complete all study visits you will receive up to a total of $150.00. If you withdraw from the study before it is completed, you will receive $50.00 for each completed visit. A completed visit means all scheduled study procedures have been carried out.

COMPENSATION FOR RESEARCH-RELATED INJURY

All contact lenses have side effects. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the study doctor and/or research study staff will assist you in obtaining appropriate medical treatment, but this study has

not set aside financial assistance for additional medical or other costs, such as lost income due to time away from work.

Should you require medical treatment as a direct result of your participation in this study, it will be provided to you at no charge by CooperVision, Inc., but neither the study doctor nor CooperVision, Inc., will automatically provide any other compensation to you. If you are harmed due to someone's negligence, then you may have grounds for legal action. You do not waive any of your legal rights by participating in the study. If you wish to pursue legal action, you agree to bear all the costs associated with making any claims.

If you are injured as a direct result of taking part in this study, emergency medical care will be provided by the study doctor, or by transporting you to your personal doctor or medical center. Neither your doctor nor the federal government will be able to provide you with long-term medical treatment or financial compensation except as may be provided through your insurance programs or through whatever remedies are normally available at law.

OHIO STATE LIABILITY

If you are injured as a result of your participation in this study, you may obtain immediate care at The Ohio State University Wexner Medical Center. The cost of this treatment will be charged to you or your insurance company. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. The Ohio State University has no funding set aside for the payment of health care expenses for this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM STUDY

Your decision to participate is entirely voluntary. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision to be in this study or to withdraw from the study. If you decide to withdraw from the study, please talk to the study doctor to make sure this is done safely. You will be asked to sign the study exit form.

Your participation may be stopped without your consent by the study doctor or the FDA for any reason. For example, your participation may be stopped:

- if it is deemed to be in the best interest of your health and welfare.
- if you have severe or unacceptable side effects.
- if you fail to follow instructions.

CONFIDENTIALITY

Your results will be kept as confidential as possible. Your name will not be in any publication or presentation of the results. However, monitors, auditors and regulatory agencies, such as the FDA, ISO and Institutional Review Boards may need to review study records for verification of the research study procedures and/or data without violating this confidentiality to the extent permitted by the applicable laws and regulations, and that by signing this written informed consent form, you authorize such access.

RIGHTS

You are under no obligation to participate in this study. If you agree to take part, you may still withdraw from the study at any time. You will be told of any important new information that is learned during the course of this research study, which might affect your willingness to continue participation in this study.

CONTACT INFORMATION

If you have questions, concerns or complaints about the research study or you experience a research-related injury; please contact Dr. Fogt or the study staff by phone at 614-292-8858 or 614-292-0882 (emergency only - 24 hours).

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).

SIGNATURES

I have read the above information and I consent to participate in the above study. I am aware that this decision is up to me and that I can change my mind at any time. I will be provided with a signed copy of this consent form. This consent form includes details of any potential risks, my rights as a research participant, and what is to be done to me. I have been given the opportunity to ask questions, and they have been answered to my satisfaction. I agree that the study doctor may withdraw me from the study, without my consent, in the interest of my health or welfare.

I have not waived any of my legal rights by signing this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date