Evaluation of Systane Complete for the Treatment of Contact Lens Discomfort

Study Protocol, Statistical Analysis Plan, and Consent

NCT03848221

October 22, 2019

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Evaluation of Systane Complete for the Treatment of Contact Lens Discomfort

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I. INTRODUCTION & RATIONALE

Soft contact lenses (SCL) are the most common CL modality with over 140 million users world.[1, 2] Despite many improvements in CL materials and solutions, the advent of daily disposable CLs, and the addition of rewetting drops to improve CL comfort, research has shown that between 21% to 64% of CL wearers permanently discontinue CL use because of ocular discomfort.[3-6] Contact Lens Discomfort (CLD) as defined by the Tear Film and Ocular Surface Society (TFOS) "is a condition characterized by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the CL and the ocular environment, which can lead to decreased wearing time and discontinuation of CL wear."[7] TFOS further states that CLD is a multifactorial condition that stems from both CL (e.g., material design, fit, care system) and environmental factors (patient factors, medication compliance, external environmental factors, ocular environment).[7] Ture CLD is thought to only exist while wearing the CL. Or said another way, CLD should be alleviated by CL removal, which is likely why removal is a common self-treatment.[5] While environmental factors related to the patient such as age and sex are inherent, rewetting drops or artificial tears can be used to treat tear film deficiencies associated with CLD.

In the absence of a CL, the ocular surface is covered by a complex bilayer of tears composed of the aqueous/mucin layer and the lipid layer.[8] The aqueous/mucin layer directly interacts with the ocular surface, a layer that primarily serves to hydrates the eye.[8] This layer is covered by an external lipid layer, which can be further divided into a polar lipid layer, which serves as an interphase between the aqueous/mucin layer and the nonpolar lipid layer, which interacts with the external environment and serves as a barrier to tear evaporation.[8] When a CL is applied to the eye, this ~3 µm thick layer of tears is divided into a pre- and post-CL tear layer, which likely disrupts tear homeostasis.[7, 9] Soft CLs are also known to quickly absorb tear lipids, which has the potential to deplete tear lipids needed to maintain a healthy ocular surface.[10] This theory is supported by how lipids deposited on CLs have been associated with CLD.[11] CLs them self are also associated ocular surface changes that likely induced the two primary forms of dry eye (aqueous deficient and evaporative dry eye).[12] Together, these tear factors along with the many other precipitating elements associated with CLD likely result in the characteristic decreased comfort and wear times associated with symptomatic CL wear.[7]

One first-line treatment for CLD is CL rewetting/lubricating drops.[13] The U.S. Food & Drug Administration (FDA) defines rewetting/lubricating drops in their *Premarket Notification (510(k)) Guidance document for Contact Lens Care Products* as "an in-eye solution for use with CLs" that contains "one or more active ingredients (e.g., ophthalmic demulcents) in sufficient concentration to alleviate symptoms of discomfort from CL wear by physical means."[13] Clinicians also commonly use artificial tears off label for treating CLD and the dry eye associated with CLs because new artificial tear formulations have the potential to outperform the available CL rewetting drops.[14] The FDA separately classifies artificial tears in their *Ophthalmic Drug Products for Over-the-Counter Human Use* monograph as topical drops that contain specific types of demulcents or emollients.[15] While off-label, McDonald et al. have previously shown that using a common artificial tear, Systane Ultra, before and after CL use is an effective means for treating daily disposable CL wears who have CLD.[14] Recently, a new formulation of artificial tears, Systane Complete, was released to the market. Systane Complete is a unique formulation that has combined elements from both Systane Ultra (indicated for aqueous deficient dry eye) and Systane Balance (indicated for evaporative dry eye) to create an artificial tear with an indication for aqueous deficient, evaporative, and mixed (both aqueous deficient and evaporative) dry eye. Thus, the Research Goals of this study are to determine in a randomized clinical trial if Systane Complete is able to effectively improve the symptoms and the quality of life of CLD suffers.

II. SPECIFIC AIM

We plan to accomplish our Research Goals by pursuing the following specific aims and testing the associated hypotheses:

Aim 1: Determine if Systane Complete is able to alleviate CLD in daily disposable CL wearers. Hypothesis: Subjects who are randomized to the Systane Complete treatment group will have a statistically significant improvement in ocular surface symptoms (Contact Lens Dry Eye Questionnaire-8) compared to subjects who are randomized to the no treatment group.

Aim 2: Determine if Systane Complete is able to improve the quality of life of daily disposable CL wearers. Hypothesis: Subjects who are randomized to the Systane Complete treatment group will have a statistically significant improvement in their University of Michigan Vision Correction Quality of Life (UM-VCQoL) Questionnaire scores compared to subjects who are randomized to the no treatment group.

III. STUDY DESIGN

Subjects

This two-week, two-visit study will be conducted at the University of Alabama at Birmingham (Birmingham, AL, USA), Southern College of Optometry (Memphis, TN, USA), and Lindenhurst Eye Physicians & Surgeons, PC (Amityville, NY). Subjects will be recruited from each site via clinic records, postcards, email, social network postings (i.e., Facebook), and fliers. Adult (>18 years) daily disposable CL wearers who have 20/30 visual acuity or better and who self-report CLD will be recruited for this study. Other CL modalities/wear schedules (e.g., two week and monthly replacement CLs, gas permeable CLs) and non-compliant daily disposable CL users (must replace CLs daily) will be excluded to avoid any potential confounders associated with CL care systems. Subjects will be screened with the Contact Lens Dry Eye Questionnaire (CLDEQ)-8, and subjects who have CLD (CLDEQ-8 scores ≥ 12) will be enrolled in the study.[16] Subjects will be excluded if they have known systemic health conditions that are known to alter tear film physiology (e.g., primary and secondary Sjögren's syndrome), have a history of ocular surgery within the past 12 months, have a history of severe ocular trauma, active ocular infection or inflammation, are currently using Accutane or ocular medications, or if they are pregnant or breast feeding.[17] Subjects with a condition or in a situation, which in the examiner's opinion, may put the subject at significant risk, may confound the study results, or may significantly interfere with their participation in the study will be excluded. Subjects with non-Sjögren's dry eye disease and subjects who have mild corneal scarring (no corneal elevations changes) will be allowed to participate. Subjects who currently use artificial tears will be allowed to participate, though they will be required to not use artificial tears for at least 24 hours before the baseline study visit and during the study.

Randomization & Masking

This will be a prospective, single masked, randomized, clinical trial, which will be registered with ClinicalTrials.gov. Subjects who meet all study criteria will be enrolled and randomized into the study. Subject randomization will be organized by the data coordinator (Gerald McGwin, Jr., MS, PhD) and will follow the general guidance provided by Pucker et al. and the Cochrane Eye and Vision group.[18] Dr. McGwin will create a randomization schedule utilizing blocking (given the small sample size) and stratification by site to maximize the likelihood that study participants will be equally distributed between the treatment groups and by site. Subject group assignments will be concealed in numbered envelops and distributed among the sites. After a subject is enrolled in the study and after the masked examiner has left the examination area, the unmasked study coordinator will open the envelope, place the subject in the correct group (artificial tears vs. no treatment) and educate the subject about it. The contents of the artificial tear bottle will be concealed. The unmasked study coordinator will educate the subject how to use the artificial tears (2x/day in each eye; once 10 minutes before and once directly after CL wear), and they will instruct the subject to not divulge any information related to their assigned group to the masked examiner. The study subjects will be instructed to not use other artificial tears or rewetting drops during the study.

Sample Size

CLDEQ-4 scores (Rasch validated version; max score of 18) will serve as the primary outcome for judging if Systane Complete is able significantly improve CL comfort.[19] Data from Pucker et al. suggests that the average CL wearer has a mean CLDEQ-4 score of 7.6 ± 3.8.[19] A 4-point difference in CLDEQ-4 scores will be considered a meaningful improvement in CL comfort. Therefore, 19 subjects per group will be needed to determine if there is no difference in CL comfort between the Systane Complete and the no treatment groups at the two weeks visit (power = 90%; alpha = 0.05). After adjusting for 20% dropout, a total sample size of 46 subjects (16 subjects/site) will be needed to determine if there is a statistical difference in CL comfort scores between subject groups.

The University of Michigan Vision Correction Quality of Life (UM-VCQoL) Questionnaire will serve as the primary outcome for judging if Systane Complete is able to improve a symptomatic CL wear's quality of life.[20] McAlinden and Lipson found with this questionnaire that daily disposable CL wearers had a mean OCL-QoL score of 59.86 ± 4.51.[20] A 5-point difference in OCL-QoL score will be considered a meaningful improvement in a patient's quality of life. Therefore, 18 subjects will be needed to determine if there is no difference in quality of life between subjects randomized to the Systane Complete and the no treatment groups at the two-week visit (power = 90%; alpha = 0.05). After adjusting for 20% dropout, a total sample size of 44 subjects (15 subjects/site) will be needed to determine if there is a statistical difference in CL comfort scores between subject groups. Given the larger sample size requirements for the CLEDQ-4, this study will plan to enroll 46 subjects (16 subjects/site).

Surveys and Clinical Tests

Clinical measurement will be obtained from both eyes of each subject and testing will be performed in the below order. Testing order was designed to sequentially administer the least invasive to most invasive test. This methodology will ensure that a previous procedure will have a minimal effect on all subsequent assessments.[21] Subjects will be asked to report to the study without their CLs on to minimize the effect of CL removal on the study outcomes. Steps 1 through 9 will be completed by the masked examiner.

Visit 1

1. Subject History, Eligibility, Informed Consent: Subjects will be asked to repeat the screening survey at the study visit to verify that they are still eligible for the study. All subjects will be screened with the CLDEQ-8 to verify that they are symptomatic CL wearers (CLDEQ-8 scores ≥ 12); the subjects will be specifically asked to think about the survey questions as if they were thinking about their end of day CL comfort. All relevant ocular, systemic, and surgical history will be gathered via a questionnaire developed by the investigators. This question will also ask about current artificial tear usage (brand, dosage, duration of use). Subjects will also be asked provide the study doctor with a valid CL prescription to verify that the subject is wearing daily disposable CLs. Non-eligible subjects will be dismissed at this time or rescheduled depending upon the reason for ineligibility. Eligible subjects will be enrolled, consented, and requested to sign a privacy document.

2. Questionnaires: All subjects will be asked to complete the Standardized Patient Evaluation of Eye Dryness (SPEED) because it is a validated dry eye symptoms questionnaire that asks about the most common dry eye symptoms.[22] Subjects will also be asked to complete the University of Michigan Vision Correction Quality of Life questionnaire because it is a validated quality of life survey for CL wearers.[20]

3. Visual Acuity: The subject's visual acuity will be measured with a Bailey-Lovie high-contrast (logMAR) chart or equivalent. If the patient is unable to read the 20/40 letters (0.3 logMAR), the investigator will pinhole over the patient's unaided or presenting refractive error correction (glasses) to determine the subject's visual potential.

4. Slit-Lamp Biomicroscopy: The investigator will use a slit-lamp biomicroscope to document normal and/or remarkable findings of the anterior eye structures: eyelashes (blepharitis), eyelids, conjunctiva, and cornea. Eyelids will be graded based upon a grading scale that was developed by the investigators.

5. Tear Break-Up Time (TBUT): A sterile sodium fluorescein strip will be wet with sterile saline and applied to the superior bulbar conjunctiva. The subject will then be asked to position themselves within the slit-lamp biomicroscope and blink three times, and the subject will then be asked to keep their eyes open and to not blink for as long as possible. The investigator will use a stopwatch to determine the number of seconds between the last blink and first break in the tears as viewed with a cobalt blue light and a yellow filter. The subject will then be allowed to blink normally for ten seconds before repeating the procedure. Each eye will be tested in triplicate, and the mean of each eye will be used in analysis.

6. Corneal Staining: A sterile sodium fluorescein strip will be wet with sterile saline and applied to the superior bulbar conjunctiva. After waiting for one-minute, corneal staining will be assessed with a cobalt blue light and a yellow filter. The CCLRU 0 to 4 grading scale will be used in 0.5 increments.[24]

7. Schirmer's Test I: Tear volume will be assessed with a Schirmer's Test. In brief, the strip will be placed at the temporal third of the lower eyelids. The subject will then be asked to close their eyes for five minutes. The length of wetting will then be measured and recorded in mm.

8. Meibomian Gland Expressibility & Quality: The lower eyelid will be slightly everted to determine if there are any visibly obstructed glands. The central 8 meibomian glands will then be expressed with the investigator's finger by placing it about one millimeter below the inferior lash line and applying light pressure for 15 seconds. These metrics will be graded with the grading scales from Meadows and colleagues.[25]

9. Exiting Visual Acuity: Visual acuity will be measured as described above.

10. Randomization: The masked examiner will leave the room, and the unmasked study coordinator will perform the randomization protocol described above. The unmasked study coordinator will then provide the subject with their predetermined group, educate the subject how to follow their study group assignment, and schedule the subject for their two-week outcome visit.

11. Subject Compliance: Subjects will be given a daily log to record the time of day when they use the eye drops. Subjects will be asked to record the time when they applied their CLs, removed their CLs, and the number of hours their CLs were comfortable. They will also be asked about their perceived perception of the eye drops (same, better, worse).

Visit 2

1. Repeat Visit 1 Tests: The masked examiner will administer the CLDEQ-8 and repeat procedures 2 through 9 as described above.

2. Study Completion: The masked examiner will leave the room, and the unmasked study coordinator will reveal the study details to the subjects (Systane Complete was being studied). The subject will be compensated for their time commensurate with each site's hourly rate, and they will be released from the study at this time.

Data Entry/Management

Surveys and all data will be collected via a secured web service (https://www.qualtrics.com/) at the time of the study visit. The online survey instrument will be designed on Qualtrics software. All data will be stored on Qualtrics servers, which meet the Health Insurance Portability and Accountability Act (HIPAA) standards and are secured against both physical and digital intrusion. Qualtrics will not be able to access subject's responses unless a request is made by the Data Coordinating Center to Qualtrics for assistance that would require their involvement with the data. All access is password protected, and data will only be stored electronically.

Risk to subjects, including a breach of confidentiality, is mitigated by the security measures utilized by Qualtrics. Physical access to the servers storing survey results is protected by a 24-hour security team, keycard and biometric authentication, digital surveillance, internally located server housings, and backup power generation. Data are also protected digitally by three mirrored Network Operations Centers, which monitor both local and regional networks including: points of presence, telecom facilities, routers, servers, and customer's infrastructure. Data are backed up at different locations in the compound via replication services, and nightly hard copies are generated and stored in a secure location. Workstations located inside the compound do not allow for remote access and do not contain any third-party software.

Data Analysis

Gerald McGwin, Jr, MS, PhD, Professor and Vice Chairman in the Department of Epidemiology at the University of Alabama at Birmingham, will perform the statistical analyses. All data will be analyzed with SAS Version 9.4 (SAS; Cary, NC, USA). The intention to treat analysis method will be employed. The treatment groups will be compared with respect to demographic and baseline clinical characteristics to ensure that the randomization was successful. T- and chi-square tests will be used when comparing continuous and categorical variables, respectively. If the assumptions of these tests cannot be met suitable alternative

statistical tests (e.g., Wilcoxon Rank Sum Test, Fisher's Exact Test) will be used instead. For the comparison of the primary outcome measures (CLDEQ-4 and UM-VCQoL scores), generalized linear models will be used with the follow-up measurement as the dependent variable and treatment group and baseline measurement used as independent variables. While we do not anticipate any differences between the treatment groups, this method ensures that any comparison between the treatment groups will be independent of even minor differences at baseline. Additionally, these models can account for potential differences between the treatment groups with respect to other characteristics, though we do not anticipate any such differences.

Training of Study Personnel

Prior to enrolling any subjects all examiners will meet at the Southern College of Optometry to complete protocol training developed by Andrew D. Pucker, OD, PhD. This full investigator meeting will ensure that all study investigators are performing the procedures in the same manner. Investigators will also be required to complete an online proficiency test. Data from each investigator's first subject will also be monitored by Gerald McGwin, Jr, MS, PhD for quality control before sites are allowed to enroll additional subjects.

VI. Conclusions

This project will be the first to evaluate the effectiveness of Systane Complete for the treatment of CLD in a rigorous and controlled manner. This work will also provide some of the first data on the impact of artificial tears on a CL wearer's quality of life. Ultimately, after completion of this study, clinicians will have the information needed to determine if Systane Complete is a suitable off-label treatment for patients who suffer from CLD

VIII. References

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CONSENT FORM

Title of Research: **Evaluation of Artificial Tears for the Treatment of Contact Lens Discomfort**

UAB IRB Protocol #: **IRB-300002321**

Principal Investigator: **Andrew D. Pucker, OD, PhD**

Sponsor: **Alcon Research, Inc.**

Purpose of the Research

We are asking you to take part in a research study on contact lens comfort. The purpose of this research is to investigate if using a newly-released artificial tear before and after contact lens use each day is able to improve contact lens comfort. The artificial tear being studied is a FDA approved artificial tear for patients who have dry eye symptoms. Given that artificial tears are the typical first line treatment for people who have uncomfortable eyes, using artificial tears before and after contact lens use may reduce the common discomfort symptoms associated with wearing contact lens. You will be made aware of the brand of artificial tears after the completion of the study. We plan to enroll 16 participants at UAB, 16 participants at Lindenhurst Eye Physicians & Surgeons, PC, and 16 participants at the Southern College of Optometry (46 total subjects).

Explanation of Procedures

Study visits:

You will be asked to attend two study visits. Each visit will last about one hour. You will also be asked to keep a log of your eye comfort and artificial tear use each day that you are in this two-week study.

- Visit #1: Baseline Evaluation
    - During this study visit, your history and consent to be in the study will be obtained and your eligibility for the study will be determined. You will be asked to fill out four questionnaires (CLDEQ-8, University of Michigan Vision Correction Quality of Life Questionnaires, SPEED Questionnaires, and a Study Specific Health and Contact Lens Questionnaire). The following procedures will be performed: visual acuity, slit-lamp biomicroscopy, non-invasive break-up time, corneal staining, Schirmer's test, and meibomian gland evaluation. You will then be randomized to receive artificial tears or no treatment, and you will also be giving a paper log to track your contact lens use, end of day eye comfort, and artificial tear use.

- Visit #2: Outcome Evaluation

- During this study visit, you will complete the same surveys and undergo the same testing that was performed at the Baseline Evaluation. After you complete this testing, you will be educated about the artificial tear being evaluated and then released from the study.

The diagnostic procedures used in this protocol are those that make up a typical eye examination or a dry eye evaluation. If you agree to join the study, the following procedures will be performed.

- Eligibility determination: You will be asked to provide documentation of your most recent contact lens prescription (e.g., contact lens prescription, contact lens boxes). You will then be required to complete a questionnaire to show that your contact lenses are uncomfortable.
- Questionnaires: Questionnaires will be used to evaluate dry eye, health history, and contact lens history.
- Visual Acuity: Your ability to read the eye chart will be evaluated.
- Anterior Eye Health: Your eye heath will be evaluated with a slit-lamp biomicroscope.
- Tear Film: The quality of your tears will be evaluated with sodium fluorescein (non-permanent yellow dye) and a slit-lamp biomicroscope to determine how fast your tears break up after you blink.
- Conjunctival Staining: Your eye's surface will be evaluated with sodium fluorescein (non-permanent yellow dye) and a slit-lamp biomicroscope.
- Tear Volume: A Schirmer's strip (small piece of paper) will be placed between your eye and eyelid for five minutes and the length of wetting will be measured to determine how much tears are present.
- Meibomian Gland Evaluation: The doctor will lightly press their finger against your eyelids and use the slit-lamp biomicroscope to evaluate the oil expressed from your meibomian glands.
- Randomization: You will be randomized by the data coordinator to get the artificial tear treatment or no treatment. The study doctor will be unaware of your study group assignment.
- Compliance: You will be asked to keep a log of your eye comfort, contact lens use, and treatment use.

Risks and Discomforts

This study does not pose any additional risk beyond that of a normal eye exam, and this study does not involve any inherent discomforts. If you find any of the eye tests uncomfortable, you will be allowed to stop participation in the study. There is also a small risk that the artificial tears may cause discomfort. If you find the artificial tears uncomfortable, you will be allowed to discontinue the study. You may be assigned to the no treatment group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives. If you are assigned to the no treatment group, you will not be allowed to use artificial tear during the study, which means that you cannot use anything throughout the day to help with contact lens discomfort, discomfort that may result in decreased contact lens wearing time. There is also a risk of breach of confidentiality, though precautions have been taken to avoid your confidentiality being broken.

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons, so you can be taken off of the artificial tears (if applicable) and referred for follow-up care if needed. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All materials, exams, and medical care related to this study will be provided to you at no cost during the two-week study period.

Payment for Participation in Research

You will be paid $200 at the completion of the study. A check will be mailed to you. You will be required to complete the necessary tax document to receive your payments. Ask the study staff about the method of payment that will be used for this study (e.g., check, direct deposit).

Payment for Research-Related Injuries

UAB, Lindenhurst Eye Physicians & Surgeons, PC, and Alcon Research, Inc. have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Andrew D. Pucker at (205) 975-9938 or after hours by emailing him at apucker@uab.edu.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

Given that hormonal changes occur during childbearing, which can affect eye comfort, this study is excluding any subject who is pregnant or nursing at the time of study.

Benefits

You may not benefit directly from taking part in this study. However, you will have the opportunity to try a new FDA-approved artificial tear for free. Also, knowledge gained from this research will help the medical community better understand and treat dry eye and contact lens discomfort.

Alternatives

Your alternative is to not participate in this study. There are also possible alternatives to treating contact lens discomfort with artificial tears, which include, but are not limited to switching to a different type of soft contact lens, hard contact lenses, other artificial tears/rewetting drops, and prescription dry eye medications.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Alcon Research, Inc.
- The Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP)

The information from the research maybe published for scientific purposes; however, your identity will not be given out. Your information may be used for future, undetermined research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

Voluntary Participation and Withdrawal

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: **Evaluation of Artificial Tears for the Treatment of Contact Lens Discomfort**

UAB IRB Protocol Number: **IRB-300002321**
Principal Investigator: **Andrew D. Pucker, OD, PhD**
Sponsor: **Alcon Research, Inc.**

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____