[redacted]

CLINICAL STUDY INVESTIGATIONAL PLAN

Protocol No: FC160322
Version: 1.01
Issue Date: October 3, 2018

Protocol Title: **Evaluation of the CooperVision, Inc. Invigor A and Invigor B Silicone Hydrogel Daily Wear Contact Lenses When Used for Frequent Replacement for Up to One (1) Month of Daily Wear.**

Sponsor: [redacted]

CRO/Monitor: [redacted]

Medical Monitor: [redacted]

PROTOCOL APPROVAL

FRS Representative

[redacted] _____ _____ _____
(Printed Name) (Signature) (Date)

Sponsor Representative

[redacted] _____ _____ _____
(Printed Name) (Signature) (Date)

TABLE OF CONTENTS

[redacted]

ABBREVIATIONS

AE	Adverse Event
CFR	Code of Federal Regulations
CRF	Case Report Form and eCRF for Electronic Forms
CRO	Contract Research Organization
D	Diopter
DW	Daily Wear
FDA	U.S. Food & Drug Administration
FRS	Foresight Regulatory Strategies, Inc.
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act
IB	Clinical Investigator's Brochure
ICD	Informed Consent Document
IDE	Investigational Device Exemption
IRB/IEC	Institutional/Independent Review Board / Independent Ethics Committee
ISO	International Standards Organization
MK	Microbial Keratitis
MPS	Multi-Purpose Disinfection Lens Care System
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
PHI	Protected Health Information
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event / Serious Adverse Experience
SCL	Hydrogel Contact Lens
SHCL	Silicone Hydrogel Contact Lens
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
VA	Visual Acuity

DEFINITIONS

Principal Investigator: (PI)
A duly licensed and properly trained individual responsible for the conduct of the clinical study at the study site. If a trial is conducted by a team of individuals at a trial site, the Principal Investigator is the responsible leader of the team. The PI must have the qualification of an Optometrist or Ophthalmologist.

Sub-Investigator: (SI) An individual member of the clinical study team designated and supervised by the principal investigator. The individual is able to perform critical study-related procedures and/or to make important study-related decisions. These properly trained individuals may be study coordinators, residents, research fellows or properly qualified and licensed Optometrists or Ophthalmologists.

Licensed Investigator: For the purpose of this protocol a Licensed Investigator will be an Optometrist or Ophthalmologist who possesses a current license in good standing for the State where he/she is currently practicing and participating in the clinical study.

Investigator: For the purposes of this protocol, an Investigator will be any of the individuals described in the definitions above of Principal Investigator and Sub-Investigator.

Data Collection and Entry: Data collection and entry may be performed by the Principal Investigator or any of the various levels of qualified Sub-Investigators. Only the PI or a professionally licensed Optometrist or Ophthalmologist SI may review the review visit data entered and complete the signature form at the completion of the visit.

Investigational Materials: The materials evaluated in the clinical study will be designated as either the Test or Control material. The Test material will be a new material that has not been previously cleared or determined to be substantially equivalent using the FDA's 510(k) review process. The material designated as the Control will have previously been review by FDA and has received a clearance under the FDA's 510(K) review process.

1 BACKGROUND

Hydrogel Contact Lenses (SCLs) and Silicone Hydrogel Contact Lenses (SHCLs) have been developed and marketed with a number of wear and care modalities to meet a variety of ocular health and convenience needs. These modalities include the periods of lens use and disposal wherein lenses are worn for months, weeks, or one day prior to disposal. Lenses used for more than a single use require the use of accessory lens care systems (multiple or single bottles) for lens cleaning, overnight storage, disinfection and lens rinsing prior to repeated insertion.

The Sponsor has developed a silicone hydrogel contact lens material for use in a recommended one month replacement modality. The material characteristics of this formulation place the material into the FDA Classification for Silicone Hydrogel materials of Group 5. Using this information the study is designed to evaluate the new CooperVision silicone hydrogel contact lens material (Test Lens) to demonstrate substantial equivalence to a material in the same class (Control Lens).

2 STUDY OBJECTIVE

The objective of this evaluation is to provide evidence supporting the claim that the performance of the Test Lens is substantially equivalent to that of the Control Lens when used in a one month recommended replacement, daily wear modality.

Based on previous evaluations of this lens design and material formulation and published information on the performance of other contact lenses marketed for similar uses, and based on the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses (May 1994) this is a non-significant risk study.

3 INVESTIGATIONAL PRODUCTS

Both Invigor A and Invigor B lenses are silicone hydrogel contact lenses. They will be used following a daily wear schedule with a recommended replacement schedule of one month.

3.1 Investigational Lens Names and Descriptions

Both Invigor A and Invigor B silicone hydrogel contact lenses are manufactured by CooperVision, Inc. Each study lens has a non-ionic surface and requires no surface treatment to impart wettability.

Each lens type will be available in the following powers and diameters:

Lens Powers:	-0.50 D to -6.00 D (0.25 D steps) -6.50 D to -8.00 D (0.50 D steps)
Lens Diameters:	14.2mm
Base Curve:	Each lens type has a single base curve. The base curve of the Invigor A lens is 8.5mm and the Invigor B is 8.6mm.

3.2 Lens Packaging and Labeling

Each lens blister pack is labeled with power, diameter, base curve, lot number, expiration date, quantity, lens name, sterility method/status and manufacturing location. The blister and outer packaging is identified as investigational product with the statement, "Caution-Investigational device, Limited by Federal (or US) law to Investigational use".

3.3 Lens Product Accountability

Test and Control lenses will be tracked through the use of base curve, power and lot numbers imprinted on the label. All lenses received by the investigational sites will be verified against the enclosed packing slip. All lenses dispensed to the study subjects during the investigation will be recorded on Inventory Control- Lens form. The site will be responsible for inventory management, limited access storage and continued inventory accountability. The study monitor will reconcile inventories remaining at the sites against product released to, received by the sites and used during the investigation. Procedures for the study product accountability are detailed in Section 5.8.

3.4 Indications for Use

Both Test and Control lenses are intended to be used as daily wear lenses for the correction of visual acuity in persons with non-diseased eyes with no more than 1.50 diopters of refractive astigmatism with a recommended replacement period of one month.

3.5 Subject Adjunct Products to be Used in the Study

The Test and Control lenses are designed for frequent replacement.

Johnson & Johnson Blink RevitaLens® Multipurpose Disinfecting Solution will be the primary multi-purpose lens care system for this study. Alcon Clear Care® Cleaning and Disinfection Solution will be used as an alternative for those subjects who have a history of, or present with, sensitivities or reduced wearing times associated with chemically preserved multi-purpose lens care systems. Subjects may be switched from Johnson & Johnson Blink RevitaLens® Multipurpose Disinfecting Solution to the Alcon Clear Care® Cleaning and Disinfection Solution, if required due to symptoms. Menicon Lacripure will be dispensed at the licensed investigators discretion to be used as a rinsing solution following disinfection with Alcon Clear Care® and prior to lens insertion. Minor solution related symptoms or subjective findings do not qualify as an adverse event unless accompanied by the presence of a grade 3 or greater slit lamp finding.

Investigational Sites will be provided with Eye-Cept, a non-preserved single dose rewetting drops containing an aqueous solution of sodium chloride and boric acid. Eye-Cept Rewetting Drops are the **only** rewetting drops that may be used by study subjects.

The use of over-the-counter (OTC) artificial tears while wearing lenses is prohibited in this study.

3.6 Occupational Hazards and Safe Handling

No specific occupational hazards have been identified with the use of contact lenses. Use of lenses in dry or dusty environments is discouraged. The use of lenses while swimming or soaking in hot tubs is prohibited during this study. **Handling of contact lenses should always be done with clean and dry hands.**

3.7 Storage Requirements and Expiration Dating

It is recommended that all lenses and solutions be stored at room temperature out of direct sunlight. They should not be allowed to freeze prior to use or during overnight storage as this may damage the lens material or solutions formulations. The product expiration date is printed on the immediate lens and solution packaging.

3.8 Dosage and Administration

Contact lenses are user applied devices. Only one study contact lens per eye at any one time is allowed.

3.9 Training for Use of the Study Products

The study subjects must be instructed and determined to be competent by the investigational site as to the proper handling, insertion and removal techniques, use and replacement of care systems and the proper accounting and disposal of the used lenses. Training will be in accordance with the information provided in Appendix H for each product. Patient care instructions will be provided to the subject at the time of initial lens dispensing.

3.10 Surgical and/or Medical Procedures

No specific surgical procedures are required as a part of this investigation. Standard ophthalmic examination procedures will be performed during the study visits.

4 JUSTIFICATION FOR THE STUDY

4.1 Literature Review

A review of the literature associated with hydrogel and silicone hydrogel contact lenses has indicated that the use of contact lenses is a safe and effective means of correcting visual acuity in persons with non-diseased eyes.

4.2 Summary of Preclinical Studies

Toxicological and microbiological testing as listed in the United States Food & Drug Administrations' (FDA) Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses (May 1994) as well as the appropriate normative guidance documents found in ISO 14534 have been performed on the Test Lens material. The material has been found to be suitable for clinical studies based on the results of this testing. Summaries of these results have been provided to the IRB within the Investigator Brochure as part of the protocol review. This information will also be included for Investigator review within the Site Binder. The Control Lens is an FDA-cleared device; therefore, no additional preclinical studies have been performed on this lens prior to this clinical investigation.

4.3 Summary of Previous Clinical Studies

Please refer to the Investigator Brochure for a summary of the previous clinical investigations conducted for the lenses used in this study.

4.4 Potential Risks and Benefits for Human Subjects

4.4.1 This study is considered to be non-significant risk, based on the United States Food & Drug Administration and International Standards Organization guidelines when the use is daily wear with frequent replacement during the study. The risk to the subject is also reduced based on the results of toxicology testing and the history of similar devices currently approved and marketed.

4.4.2 The risks associated with contact lens wear have been established through device evaluations and market reporting. The risks may include discomfort, dryness, aching or itching eyes, excessive tearing, discharge, hyperemia and variable or blurred vision. More serious risks may include photophobia, iritis, corneal edema, corneal infiltrates and microbial keratitis.

4.4.3 The benefits of the Test Lens to the subjects are the possibility of improved vision, improved comfort and improved ocular health over other frequent replacement contact lenses due to the design and material characteristics of the lenses.

5 CLINICAL STUDY DESIGN

This study is a multi-center, randomized, licensed investigator and subject masked, concurrent control investigation that will enroll and screen up to one-hundred (100) subjects with the intention of successfully dispensing ninety (90) subjects for a study duration of approximately three months. Only subjects meeting the historical, refractive, ocular health and lens fitting and dispensing inclusion and exclusion criteria will be allowed to complete the dispensing visit. The study duration from dispensing to completion will be a minimum of 91 days.

The design of this clinical study is based on the United States FDA Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses May 1994 and the ISO 11980:2012(E) Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations.

5.1 Investigator/ Site Selection and Qualification

Up to six (6) investigational sites will be selected based on the experience of the site investigator(s) and staff in conducting clinical research trials, the availability of potential study subjects, and the availability and interest of the site in performing the trial.

All required and appropriate, documentation to meet the ISO 14155 and FDA GCP guidelines as well as [redacted] SOPs will be completed prior to the release of the investigational products to the site. If requested in writing, [redacted] will follow the Sponsor's SOPs for clinical study documentation.

At a minimum, a signed Site/Investigator Agreement, Financial Disclosure Document, Proof of Liability Insurance (Both Site and Sponsor Indemnification) Statement of Investigator Document, IRB approval letter, Delegation of Authority, Certification of Electronic Signature and Site Electronic Data Originators Authorization Log must be completed. Documents must be received by [redacted] the [redacted] Study Monitor prior to investigational material being released to the study site.

5.2 Measures to Avoid Bias

Measures to control bias include the use of multiple investigational sites, licensed investigator and subject masking of the Test and Control lenses, and randomization of assignment of the Test and Control lenses. The subject will know the name of the lens however they will not be aware of which lens is investigational and which lens has been previously cleared. The licensed investigator has not been informed which lens is the investigational lens. Due to a 2:1 ratio of Test to Control Lenses in the study, the study coordinator will not be completely masked, but efforts will be made by the study coordinator to maintain masking of the licensed investigator. It is possible that the licensed investigator may notice the slight visibility tint in the Invigor A lenses but since it is not obvious the likelihood of any introduction of bias is extremely unlikely.

5.3 Randomization

Subjects will be randomized into the study contact lenses in a two to one (2:1) ratio of Test to Control subjects. This should result in a study population of approximately 60 Test subjects and 30 Control subjects. Randomization is designed to maintain this ratio of Test and Control lens subjects within each investigational site. Randomization will be presented to the Study Coordinator through the tablet software with a pre-determined randomization for each site. A subject will be randomized based on the order in which the subject is enrolled and progresses through the inclusion/exclusion criteria leading up the point of randomization.

5.4 Study Endpoints

The safety and efficacy endpoints are detailed below.

5.4.1 Safety Endpoints

The primary safety endpoints will be a comparison of the slit lamp findings [redacted]

5.4.2 Efficacy Endpoints

The primary efficacy endpoint in this evaluation will be a comparison of the reported Snellen distance visual acuities as associated with the Test and Control lenses during scheduled visits. It is expected that the lens Snellen distance visual acuity results will be substantially equivalent between the Test and the Control lenses.

In addition, visual acuity with the Test and Control Lenses at the final study visit will be compared to the Test and Control Lens visual acuity at the Fitting visit. All changes ≥2 lines of visual acuity will be explained and compared across the Test and the Control lens groups. It is expected that the results will be substantially equivalent between the Test and the Control lens groups.

[redacted]

5.5 Methods and Timing for Assessing, Recording and Analyzing Data

The study design calls for a series of scheduled visits, bounded by specific observational windows, at which the study variables will be assessed using standard ophthalmic examination techniques, and recorded using electronic data capture. It is desirable to collect scheduled visit data with at least four (4) hours of lens wear at the time of scheduled follow-up visit.

Monitoring of the data will be routinely performed during the study while there are active subjects. Remote monitoring will be continuously performed to review the case report form data for individual subjects. Data analysis of the study variables will be performed following the completion of the study at a time when all subjects have exited the study. The study database must be cleaned, audited and locked prior to final analysis.

5.6 Equipment Used for Assessments

Each site must have the maintenance records (both preventive and equipment failure) and where appropriate the calibration records **(within the last 12 months)** for equipment used to perform standard ophthalmic examinations. This includes but is not limited to:

- Phoropter (manual or automatic) or trial lens frame and lenses.
- Snellen Visual Acuity Charts calibrated for the appropriate test distance. **
- Keratometer (manual or automatic) – topography or corneal mapping equipment may be used for assessing keratometric measurements as long as the same instrument and function are used for all subjects at all visits. **
- Lensometer: (manual or automatic) **

- Slit Lamp Biomicroscope or Videoscope

  ** Calibrations records required to be maintained in Investigational Site files.

Grading scales for recording the observations are provided in Appendix E.

5.7 Investigational Lens and Comparator

This study has one investigational (Test) silicone hydrogel contact lens, and one FDA cleared comparator (Control) silicone hydrogel contact lens.

5.7.1 Investigational Test Lenses

The Test Lens is an investigational contact lens manufactured by CooperVision Inc.

5.7.2 Comparator Control Lenses

The Control Lens is a contact lens currently marketed and manufactured by CooperVision Inc. The Control Lens was chosen because it has been cleared by FDA for daily wear with a frequent replacement and has a known safety profile.

5.7.3 Exposure to Study Lenses

Study subjects are dispensed with either the Test or the Control lenses. The subjects will use the lenses for daily wear with frequent replacement schedule of one month. If needed, the licensed investigator may adjust the replacement schedule to a shorter replacement schedule to improve the wearing experience or ocular health of the subject. Reasons for prescribing a shorter replacement cycle will be documented on the comments section of the eCRFs. The subject's total exposure to the lenses will be based on each subject's reported daily lens wearing time, average days worn per week and length of time in the study.

5.7.4 Concomitant Medication/Treatment

No concomitant medications or treatments are planned for use in this study.

5.7.5 Anticipated Number of Study Lenses Used

It is anticipated that approximately 600 Test Lenses will be used by 60 subjects (120 eyes) and approximately 300 Control Lenses will be used by 30 subjects (60 eyes) during the three-month study period.

The number of lenses projected for use by both the Test and the Control subjects over the duration of the study (average 10 lenses per subject) is based on the fact that the lenses are intended to be discarded at the Month 1, Month 2 and Month 3 visits. Therefore, each subject successfully completing the study is expected to use a minimum of 3 lenses per eye, six (6) lenses in total, during the 3-month (91 Day) period. In addition, subjects may replace lenses for a variety of reasons during the study, raising the lens usage totals. Reasons for all lens replacements including scheduled replacements will be captured on the Lens Usage Cards. These cards will be issued to the study subjects as needed and reviewed by the study coordinator at each study follow-up visit.

5.7.6 Assessment of Compliance

Subject compliance to the daily wearing schedule and frequency of lens replacement will be assessed by the investigational sites during each study follow-up visit.

Any subject found to be non-compliant with the study protocol will be reinstructed as the correct procedures. If the licensed investigator believes the subject is unwilling or unable to be compliant, the licensed investigator may exit the subject at any time. If the subject continues with non-compliant behavior at the next scheduled visit, the subject should be exited from the study.

5.8 Study Material Accountability

All study lenses must be inventoried upon receipt by the investigational site and stored in a secure area, segregated from any other materials, and issued only as directed in the protocol.

The investigational site must document the dispensing and return (**unused lenses only**) of each investigational lens (Test and Control) for each subject using the Inventory Control-Lens form provided in each subject's study record on the tablet.

Study subjects must discontinue wearing the study lenses at the exit visit and all used lenses regardless of age must be discarded at the exit visit. All unused lenses must be returned to the investigational site and recorded on the subject's Inventory Control-Lens form. The lenses dispensed per eye must be equal to the sum of the lenses returned plus the lenses used and discarded during the study.

Investigational material accountability will be checked by the study monitor during a site closeout visit. All unused lenses, not dispensed or returned by the study subjects, must be retained at the study site until accountability has been checked and reconciled by the study monitor. Any discrepancies in study lens accountability must be explained and documented by the study coordinator. After the study monitor has verified material accountability, any unused materials will be returned to FRS or the Sponsor unless the principal investigator is otherwise directed in writing by FRS or the study Sponsor.

5.9 Informed Consent

A legally constituted Informed Consent Document (ICD) must be presented to the subject with sufficient time to read, ask questions and receive answers to make an informed decision regarding participation in the study. The Informed Consent Document must be understood and signed by each study subject prior to the subject being enrolled in the study. The individual explaining the Informed Consent Document must have full knowledge of the protocol, must be authorized by the principal investigator to explain the protocol requirements to the subject and must sign the document. A licensed investigator must also sign the Informed Consent Document and provide a copy to the subject prior to treatment.

5.10 Study Subjects

The dispensed study population will include up to 90 subjects who require a bilateral vision correction (180 eyes) randomized into the study contact lenses in a ratio of two to one (2:1) Test to Control subjects. This should result in a study population of approximately 60 Test subjects and 30 Control subjects.

The completed subject population is expected to include at least 50 Test subjects and 25 Control subjects. There are no provisions for replacing randomized subjects who are discontinued from the study.

To be eligible for study material randomization, a subject must have ALL of the Inclusion Criteria and have NONE of the Exclusion Criteria for initial screening/subject history, refractive assessment and ocular health findings. To be eligible for lens dispensing, the subject must have at least 20/30 VA in each eye with the study lens and the licensed investigator must judge the fit as acceptable or optimal.

5.10.1 Subject History Inclusion Criteria

Prior to being considered eligible to participate in this study, each subject **MUST**:

1. Be at least 18 years of age as of the date of evaluation for the study.
2. **Have:**
   a. **Read the Informed Consent Document**
   b. **Been given an explanation of the Informed Consent Document**
   c. **Indicated understanding of the Informed Consent Document**
   d. **Signed the Informed Consent Document**
3. Be willing and able to adhere to the instructions provided by the investigational site and be willing and able to keep all specified appointments.
4. Be an adapted, frequent replacement, current full-time silicone hydrogel or soft contact lens wearer. An adapted full-time wearer is defined as wearing contact lenses at least 5 days per week for at least 8 hours per day for at least one month prior to participation in the study.
5. Possess or obtain prior to dispensing, wearable and visually functional (20/40 or better) eyeglasses.
6. Be in good general health, based on his/her knowledge.

5.10.2 Subject History Exclusion Criteria

Subjects may not be enrolled in this study if any of the following apply: The subject is currently or has:

1. Wearing lenses in a monovision modality and is unwilling to be fit with distance lenses in both eyes for the duration of the study. **NOTE: Subjects may not wear lenses in a monovision modality at any time during the study as it will interfere with the visual acuity analysis.**
2. Poor personal hygiene.
3. Any active participation in another clinical trial during this trial or within 30 days prior to this study.
4. To the best of the subject's knowledge, she is currently pregnant, is lactating or is planning a pregnancy within the next 3 months.

5. A member, relative or household member of the investigator(s) or of the investigational office staff.
6. A known sensitivity to the ingredients used in the MPS approved for use in the study and is unable or unwilling to use the alternate care system.
7. Had previous refractive surgery; or current or previous orthokeratology treatment.
8. Aphakic or pseudophakic.
9. Ocular or systemic disease such as, but not limited to: anterior uveitis or iritis (past or present), glaucoma, Sjögren's syndrome, lupus erythematosus, scleroderma, keratoconus or uncontrolled diabetes.
10. The need for topical ocular medications or any systemic medication which might interfere with contact lens wear or require the lenses to be removed during the day.
11. A known history of corneal hypoesthesia (reduced corneal sensitivity), corneal ulcer, corneal infiltrates, iritis, bacterial or fungal infections.
12. A history of papillary conjunctivitis that has interfered with contact lens wear.

5.10.3 Refractive Assessment Inclusion Criteria

Does the subject

1. Require spectacle lens powers between -0.50 and -8.00 diopters sphere with not more than 1.50 diopter of refractive astigmatism and be willing to wear contact lenses corrected for their full distance prescription in both eyes.
2. Have manifest refraction Snellen visual acuity equal to or better than 20/25 in each eye.

5.10.4 Ocular Health Assessment Exclusion Criteria

Does the subject have

1. Clinically significant (grade 2, 3 or 4) anterior segment abnormalities; or the presence of any infection of the eye, lids, or associated structures.
2. Pathological dry eye or associated dry eye symptoms with decreased tear levels and punctuate staining $\geq$ Grade 2
3. Pterygium
4. Corneal scars within the visual axis
5. Neovascularization or ghost vessels $\geq$ 1.0 mm in from the limbus
6. Giant papillary conjunctivitis of $\geq$ Grade 2
7. Any inflammations such as anterior uveitis or iritis
8. Seborrheic eczema, seborrheic conjunctivitis or blepharitis

5.10.5 Lens Fitting and Training-Dispensing Inclusion Criteria

1. Does the subject achieve Snellen visual acuity of 20/30 or better with the study lens and the licensed investigator judges the fit as acceptable or optimal in each eye?
2. Has the subject been completely trained in the use of the lens care system?
3. Is the subject proficient in the insertion and removal of the lenses?

5.10.6 Vulnerable Populations

This study includes no specific vulnerable populations. All subjects are expected to be at the age of majority as defined by the State or Commonwealth of the investigational site and have the ability to freely consent to participate in the study.

5.11 Subject Discontinuation

A subject's study participation may be discontinued at any time if, in the opinion of the subject, the licensed investigator, the IRB, or the Sponsor, it is the best interests of the subject. Any female subjects who become pregnant during the study must immediately disclose this fact to the licensed investigator and will be immediately exited from the study.

5.12 Procedure for Replacing Subjects

There is no procedure for replacing the study subjects who meet all the inclusion/exclusion criteria for randomization. The enrolled study population includes a surplus of subjects to account for the expected screen failures and discontinued subjects.

5.13 Duration of the Investigation

The overall duration of the investigational study will include the study enrollment period of approximately 4 weeks, plus the subject minimum follow-up period of 91 days (up to 15 weeks), resulting in an overall study duration of approximately 19 weeks.

5.14 Premature Study Termination or Suspension

The clinical study may be suspended or terminated by the Sponsor and/or the reviewing IRB at any time if, in the opinion of the Sponsor or the IRB, it is in the best interests of the study participants.

If the decision is made to terminate the study, all sites will be notified to call in the study subjects, perform a final study examination, collect all of the study materials and complete study exit forms and documentation.

5.15 Data Monitoring Committee Information

There is no Data Monitoring Committee for this investigation. Data review for safety will be the responsibility of the Medical Monitor.

6 STUDY PROCEDURES

6.1 Enrollment Procedures

Each subject who is considered for the study must be presented with the Informed Consent Document, allowed sufficient time to read the document, ask any questions that may arise and/or have the document and the consent explained to them, and then sign the Informed Consent Document prior to being examined for eligibility for the study.

If the subject is unable to read the document but is able to understand the information, the consent may be presented and explained by a licensed investigator in the presence

of a witness. If the subject understands and is in agreement, all three (licensed investigator, subject and witness) must sign the document.

The Informed Consent Document must be understood and signed by each study subject prior to the subject being enrolled in the study. The individual explaining the Informed Consent Document must have full knowledge of the study protocol, have been authorized by the principal investigator and must also sign the Informed Consent Document. A copy of this document will be provided to each subject and a copy will be retained in the study Site Binder.

All subjects who sign an Informed Consent Document are considered to be enrolled into the Clinical Study ("Point of Enrollment").

6.2 Screening, Randomization/Trial Fitting, Training/Dispensing

6.2.1 Screening

The subject's ocular and general health history will be reviewed with the subject against the historical inclusion/exclusion criteria. If the subject meets all the historical inclusion and has none of the exclusion criteria, the exam may proceed to the collection of refractive and ocular health information. A licensed investigator will then review the inclusion/exclusion criteria for these areas.

6.2.2 Randomization/Trial Fitting

If a subject is found to be eligible and expresses interest in participating in the study, the subject will be randomized into one of the study materials. The appropriately randomized material will be placed on the subject's eyes by the study coordinator or by the subject under the study coordinator's supervision. An evaluation of the lens visual acuity, over refraction, resulting visual acuity and lens fit will be performed by a licensed investigator following 10 minutes of adaptation. Up to three lenses per eye may be used to optimize the visual acuity.

Subjects can only be considered for lens training/dispensing if:

1. They have an acceptable or optimal fit as judged by a licensed investigator and
2. Their Snellen Visual Acuity with the study lenses is equal to or better than 20/30 in each eye.

6.2.3 Training/Dispensing

If the subject meets the inclusion criteria for the fitting visit, the site may begin training the subject in the use of the study care solutions and the techniques for insertion and removal of the lenses. The subject must demonstrate a proficiency in the insertion and removal of the study lenses as well as an understanding of the use of the assigned care system. Dispensing will be considered to be the act of allowing the subject to leave the office with the lenses and care system as they have mastered the act of independent lens care. Follow-up visits should be scheduled prior to allowing the subject to leave the office.

Inclusion criteria for the Training/Dispensing Visit are

1. The subject must demonstrate an understanding of the use of the study care system provided to them.
2. The subject must demonstrate the ability to handle, insert and remove the lenses.

6.3 Study Visit Schedule and Procedures

The study duration is planned for approximately three months for each subject with examinations at the Initial visit, Fitting Visit, Training/Dispensing visit, and Scheduled follow up visits at week-1, week-2, month-1, month-2 and month-3. The dispensing visit date is the basis for scheduling all following visits and for the purpose of counting scheduled follow up visits this is considered day 0 of the study. For the purpose of counting lens wearing days in the study, the day the subject starts to wear the study lenses is day 1 of lens wear. The week-1, week-2 and monthly follow up visits will have visit windows that are based on the dispensing visit date as day 0.

6.3.1 Scheduled Visit Windows

The week-1, week-2 and monthly follow up visits will have visit windows that are based on the time from the dispensing visit date as follows:

Table 1: Examination Visit Windows

Days from Dispensing (Day 0)		
	Earliest	**Latest**
Week 1	5	9
Week 2	12	16
Month 1	26	34
Month 2	56	64
Month 3	91	105

Scheduled visits will be the first visit within the visit window where the subject presents wearing lenses. Visit schedules will be calculated at the time of dispensing by the tablet software and available to the investigational site for scheduling follow-up visits.

6.3.2 Unscheduled Visits

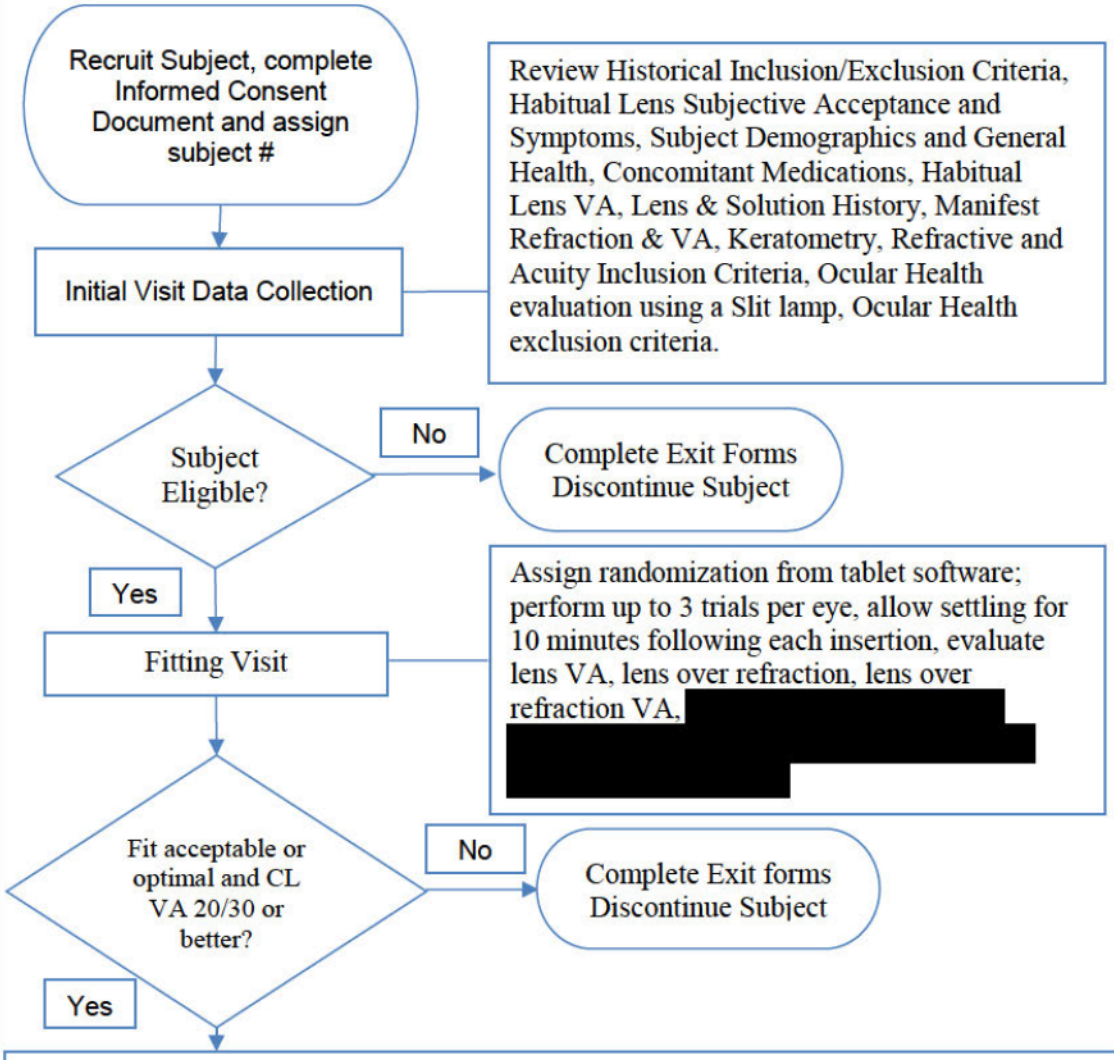
Subjects who present without wearing lenses within a visit window, a visit that fall outside of the specified visit windows or repeat visits within a visit window will be classified as unscheduled visits for analysis purposes. The Unscheduled visit examination must be completed as much as possible and the reason for the unscheduled visit must be recorded.

6.3.3 Detailed Description of Study Visits and Clinical Measurements

The data to be collected and the forms to be completed at each study visit are presented in Figures 1 and 2 and in Table 2 and Table 3.

Figure 1: Initial, Fitting, Training-Dispensing Visit Flow Chart

Procedure: Recruit, Sign Informed Consent Document, Assign Subject Number, Determine Eligibility by inclusion/exclusion criteria, collect subject demographic, personal health information and CL history, perform refractive and ocular health examination, randomize, trial fit, master lens handling and care, schedule follow-up visits.
Visit Forms: Informed Consent Document, Create Subject, Visit Date, Historical Eligibility, Subjective Acceptance, Symptoms, Baseline, Slit Lamp, Slit Lamp Eligibility, Inventory Control-Lens, Fitting, Training-Dispensing, Solutions Details, Visit Sign Off, Optional: Concomitant Medications, Adverse Event-Initial, Adverse Event-Follow Up, Notes, Exit, Exit-Lost to Follow-up, Lens Replacement Card, Lens Replacement Form



Training-Dispensing Visit: The subject will be instructed on personal hygiene, the handling, insertion, removal, cleaning, overnight storage and disinfection of the study lenses with the assigned lens care system. Licensed investigator must judge Lens Fitting and Training-Dispensing Inclusion criteria. Once the subject has met the inclusion criteria, they will be considered acceptable for lens dispensing. They may leave the office with the lenses and be scheduled for study follow-up visits. They will receive a Lens Replacement Card at this time. If the subject fails to master any of the tasks, they will be exited from the study.

Figure 2: Follow-up Visit Flow Chart

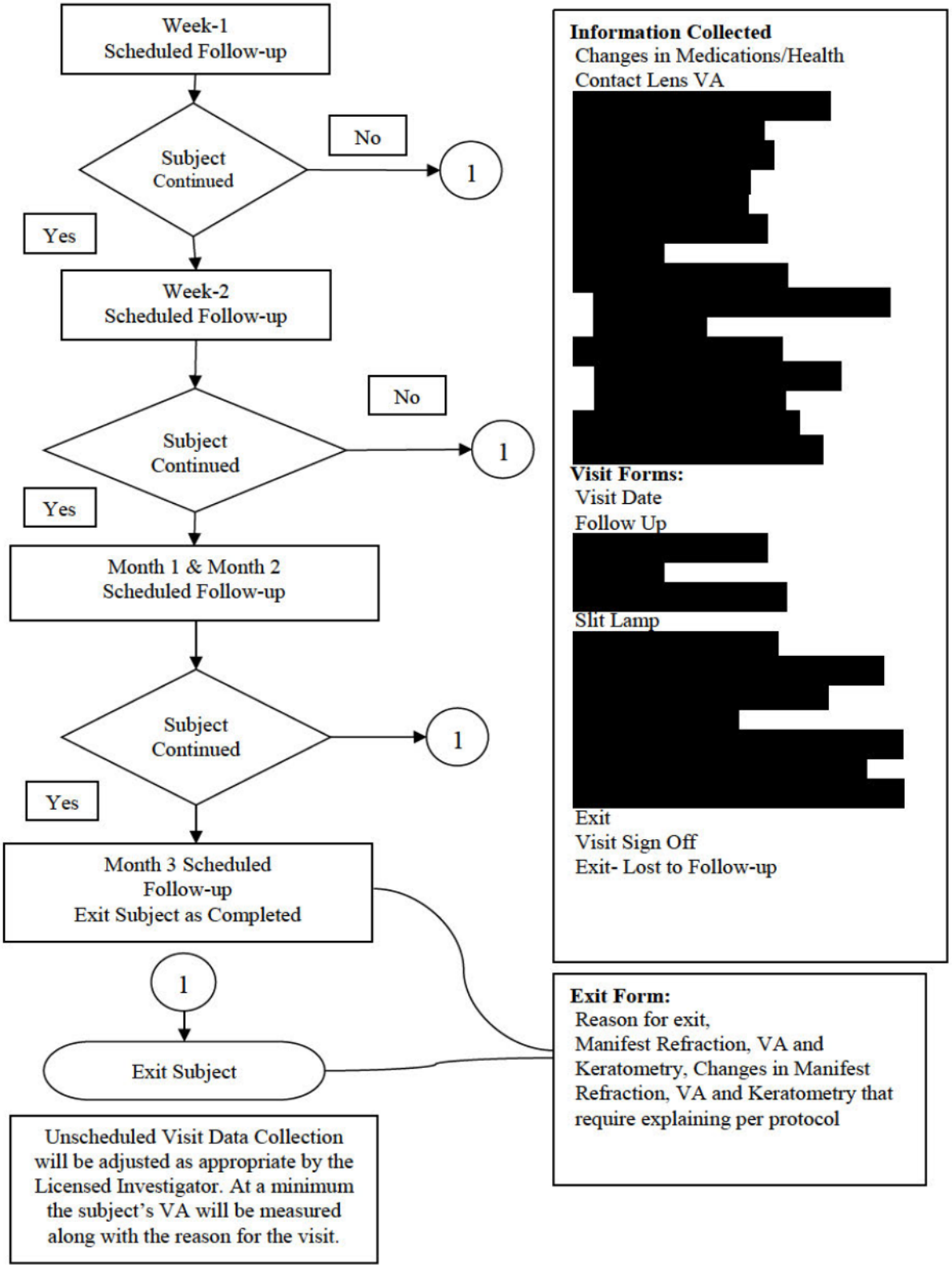


Table 2 Examination Forms by Visit

Forms to Complete	Initial, Fitting, Training/Dispensing Visits			Follow-up Visits		Lost To Follow Up
	Initial	Fitting	Training/ Dispensing	Scheduled	Unscheduled[b]	
Informed Consent Document	X					
Create Subject	X					
Visit Date	X	X	X	X	X	
Historical Eligibility	X					
Baseline	X					
Inventory Control- Lens		X[d]	X[d]	X[d]	X[b, d]	
Fitting		X[c]		X[g]	X[g]	
Training/Dispensing			X			
Slit Lamp	X	X[g]	X[g]	X	X	
Slit Lamp Eligibility	X					
Subjective Acceptance	X		*	X	X[b]	
Symptoms	X			X	X[b]	
Lens Replacement Form				X	X[b]	
Solutions Details				X	X[b]	
Follow-up				X	X	
Adverse Event-Initial	X[e]	X[e]	X[e]	X[e]	X[e]	
Adverse Event-Follow Up		X[e]	X[e]	X[e]	X[e]	
Concomitant Medications	X[g]	X[g]	X[g]	X[g]	X[g]	
Fit & Surface Evaluation		**		X	X[b]	
Visit Sign Off	X	X	X	X	X	X
Exit	X[a]	X[a]	X[a]	X[a]	X[a]	
Exit-Lost to Follow Up						X[a]

X Indicates the form to be completed

a Exit visit – subject discontinuation may occur at any time during the study process.

b Unscheduled visit – certain visit procedures may be omitted if in the Subject's best interest.

c Randomization of the Subject to a specific lens group occurs at the Fitting visit only.

d Lens accountability must be recorded any time lenses are tried or dispensed to a Subject and any time unopened lenses are returned by the Subject.

e Adverse Event forms must be completed at any time an adverse event is noted and each time the subject is evaluated until the event is resolved.

f Visual acuity **must** be recorded at **every** visit for **each** eye with either contact lenses, glasses or unaided.

g As Appropriate

* Subjective Assessment is captured as part of the Training/Dispensing Form.

** Fitting and Surface Evaluation information is collected as part of the Fitting Form

Table 3 Evaluation/Measurement/Information Collected

Evaluation/Measurement/Information to be Recorded		Initial, Fitting, Training/Dispensing Visits			Follow-up Visits		Exit Visit
		Initial	Fitting	Training/ Dispensing	Scheduled	Unscheduled	
Informed Consent		X					
Randomization			X[c]				
Eligibility Evaluation	Inclusion Criteria	X	X	X			
	Exclusion Criteria	X					
Subjective Acceptance	Habitual Lens	X					
	Study Lens			X	X	X[b]	
Symptoms		X			X	X[b]	
Subject Medical History and Demographics		X					
Habitual Lens VA, Lens Wearing History and Habits		X					
Spectacle or Unaided VA						X[f]	
Manifest Refraction, Best Spectacle-Corrected VA or Unaided VA		X				X	X
Lens VA & Over-Refraction, Best Corrected Lens VA			X		X	X[b]	
Keratometry		X					X
Slit Lamp		X	X[g]	X[g]	X	X	
[redacted]		[redacted]			[redacted]	[redacted]	
[redacted]		[redacted]			[redacted]	[redacted]	
[redacted]			[redacted]		[redacted]	[redacted]	
[redacted]			[redacted]		[redacted]	[redacted]	
[redacted]					[redacted]	[redacted]	
[redacted]			[redacted]	[redacted]	[redacted]	[redacted]	
Adverse Event Documentation		X[e]	X[e]	X[e]	X[e]	X[e]	X[e]
Reason for Exit		X[a]	X[a]	X[a]	X[a]	X[a]	X[a]

Refer to Legends from Table 2

6.3.4 Recording Source Data

Electronic tablet (iOS or Android) entry using [redacted] software will be performed in lieu of paper. Notes or paper records should avoided whenever possible. All paper record keeping must be scanned and provided [redacted] for attachments to the appropriate visit forms. Sites are encouraged to enter all study data directly on the electronic tablet during the subject visit.

If for any reason study notes are recorded on paper the notes must be signed and dated and placed in the subject's medical record as a source document. Copies of this information should be provided [redacted] for attachment to the study visit forms. Enter all study data as required for each visit. Upload of the study data to the central study database will be performed automatically during the study visit or manually at the completion of the study visit. Each page of each visit form except for the Inventory Control-Lens form, **must be reviewed** by the licensed investigator prior to accepting and sign-off of the source documents. All visit forms remain on the electronic device until the completion of the study. Following the study completion and reconciliation of all queries; a DVD with PDF copies of the site Case Report Forms will be supplied to the study site.

When using paper documents, ballpoint pen with **permanent** blue or black ink must always be used when recording data on study-related documents. Pencil or felt-tip pens **MAY NOT** be used.

Writing should be done firmly and legibly to ensure that the notations can easily be read, with no stray, confusing or obscuring marks. The investigational site is responsible for ensuring that the source documents are legible and complete.

NOTE: If any study information is collected using an automated piece of equipment, the information should be recorded directly onto the entry screen from the instrument display or printed output.

If the automated instrument HAS a printed output, the printed output MUST be kept in the subject's medical file as a source document with the subject number, date of recording and signature of the authorized individual completing the test. For thermal paper whose image is unstable, a copy of the printout can be produced with the same information printed and signed on the copy page so as to be an original document. A copy must be supplied [redacted] for attachment to the appropriate eCRF.

Lens Replacement Card Must be kept with the subject's Informed Consent document in the site binder as a source document.

6.3.5 Corrections or Changes to Study Data

As with all visit information, the licensed investigators **do not have access to view** the study investigational product information. Any corrections to the inventory information can only be performed by those who are designated as "Study Coordinators" under the Duties and Responsibilities detailed in the [redacted] Site Personnel & Delegation Log.

Corrections or changes may be made to all the remaining data entered onto an electronic tablet prior to or following acceptance and synchronization. Corrections or changes that need to be made to data after the data has been approved by the licensed investigator will be performed using the query function of the application. Corrections may be attributable to any site personnel authorized to enter data. Final acceptance of any queries and the changes contained within, **must be approved by the signature of**

the licensed investigator who completed the original visit or if that person is no longer available, the Principal Investigator may sign in their absence.

The data will be changed in the database with a complete history tracking of all information containing the change, the person making the change, the date and time of the change and the reason for the change. This information will be maintained in the data base as part of a data entry audit trails. Once reviewed and approved by the licensed investigator the corrected case report form image will be available to the investigational site for inclusion in the subject's medical record.

6.4 Criteria and Procedures for Subject Exit

A subject's study participation may be discontinued at any time if, in the opinion of the subject, a licensed Investigator, the IRB, or the Sponsor, it is in the best interests of the subject. Any female subjects who become pregnant during the study must immediately disclose this fact to a licensed investigator and will be immediately discontinued from the study.

Upon discontinuation from the study, subjects must return all unused study lenses to the investigational site.

6.4.1 Reasons For Exit

0. Study Completed

Possible reasons for discontinuation include:

1. Screen Failure – the subject does not meet the protocol specified inclusion criteria or has one or more of the exclusion criteria present.
   1.1. Previous History
   1.2. Refractive Assessment
   1.3. Ocular Health Assessment
   1.4. Trial Lens Fitting
   1.5. Trial Lens VA
   1.6. Trial Lens Comfort
   1.7. Subject was unable to insert/remove lenses or use care system
   1.8. Licensed Investigator Decision
   1.9. Subject Decision
2. Unacceptable Lens Fit – the subject is exited from the study due to an unacceptable lens fit at a visit following dispensing.
3. Unacceptable Visual Acuity – the subject is unable to obtain or maintain acceptable visual acuity with the study lenses at a visit following dispensing.
4. Unacceptable Lens Comfort – the subject is exited from the study for comfort reasons at a visit following dispensing.
5. Objective Ocular Findings – the subject has been exited from the study due to objective ocular findings that are not specifically cited as adverse events. The reason for discontinuation should indicate the relationship (related, unrelated or unknown) of the findings to the study lenses. The reason for discontinuation must be recorded in the comments section of the Exit Form.

6. Adverse Event – the subject has been reported to have an adverse event and was discontinued due to the adverse event.
7. Other: Subject Decision – the subject decides for reasons other than those listed to exit from the study. The reason must be recorded in the comments section of the Exit form.
8. Other: Licensed investigator, sponsor or IRB Decision – the subject is exited from the study based on a decision by the licensed investigator, the Sponsor or the reviewing IRB. The reason for discontinuation must be recorded in the comments section of the Exit Form.
9. Protocol Deviation – the subject or the investigational site is repeatedly found to be in deviation of the study protocol.

   NOTE: Subjects who become **pregnant** while enrolled in the study must notify a licensed investigator and be discontinued from the study as a **Protocol Deviation.**
10. Lost to Follow-up – the subject fails to return for follow-up visits. To classify a subject as "Lost to Follow-up" attempts must be made to reach the subject by the appropriate means of communication for this subject. This may include phone, fax, email or text messaging. Failing to reach the subject with any of these approaches, the site should attempt to notify the subject by a certified email to their last known address with a return receipt. Details of the attempts to contact the subject and if available, the details of why the subject is considered Lost to Follow-up must be recorded in the comments section of the Exit-Lost to Follow Up form.

6.4.2 Data to be collected at Exit

A complete follow-up examination should be documented for each subject on the date of exit. If the subject is lost to follow-up, the Exit-Lost To Follow Up form should be completed with the date of the last visit subject seen as the exit date.

6.4.3 Visit Requirements for Subjects Exited Prior to Study Completion

Subjects who discontinue the use of the assigned study lens for an adverse event or ocular findings must be followed as active subjects until the condition has resolved, returned to pre-study status or in the opinion of the licensed investigator warrants no additional follow-up as the outcome has become permanent.

If the subject must be followed beyond the 3 month study period, unscheduled visits must be conducted until the condition has resolved, returned to pre-study status or in the opinion of the licensed investigator warrants no further follow-up as the outcome has become permanent.

If the resolution has not occurred within 6 weeks following the study end-date, the subject will be exited from the study but must continue to be followed by the licensed investigator until the condition has resolved, returned to pre-study status or in the opinion of the licensed investigator warrants no further follow-up as the outcome has become permanent.

6.5 Adverse Event Reporting and Management

All Serious, Significant or Unanticipated Adverse Events must be reported to the Medical Monitor [redacted] within 24 hours of the licensed investigator initially becoming aware of the event.

Serious, significant or unanticipated adverse events, whether vision is impaired or not, will be documented in a written report and submitted by a licensed investigator to their respective Institutional Review Board with a copy sent to the Medical Monitor, by **fax, secure email with a receipt or express mail** within **ten (10)** working days of the licensed investigator initially becoming aware of the event.

Such a report will include a statement on whether or not the adverse event was considered study device related. The IRB can suspend or withdraw its approval if the cumulative data on adverse events indicates that continuation of the study is not appropriate for human subject safety.

Non-significant adverse events should be reported to the Medical Monitor within the normal timeframes for CRF submission and these will be included in a quarterly report to the Sponsor and the closeout report to the IRB at the conclusion of the study.

[redacted]

6.6 Criteria for Study Completion

Subjects will be counted as completed when they have completed the Month 3 visit of the study and have been exited from the study as Completed.

6.7 Medical Care for Subjects after Study Completion

No continuing medical care will be provided for subjects after study completion except for the care required to follow-up and resolve an adverse event that started during the study.

7 STUDY MONITORING

7.1 Monitoring Plans

A monitoring plan has been prepared for this study and is on file with [redacted] the study Sponsor.

7.2 Access to Source Data and Source Data Verification

The investigational site will allow the study monitor(s), sponsor representatives and/or authorized members of the IRB to observe procedures and inspect study records and subjects' medical records throughout the study to verify protocol compliance, case report completeness and investigational material accountability.

Should the investigator or investigational site be found to be non-compliant and unwilling or unable to convert noncompliant practices, it is the Sponsor's obligation to terminate that investigator's or investigational site's role in the investigation and the IRB will be notified.

8 STATISTICAL CONSIDERATIONS

8.1 Study Design, and Analytical Method

The primary objective of this evaluation is to provide evidence supporting substantial equivalence for the primary safety and efficacy variables of the Test Lens compared to the currently cleared and marketed Control Lens when used in a daily wear modality with an anticipated replacement period of approximately 30 days wear.

8.2 Sample Size Justification

The completed subjects sample size for this study is planned to be 50 Test Lens subjects and 25 Control Lens subjects based on a two to one (2:1) ratio of Test Lens subjects to Control Lens subjects.

The sample size for this study is based on the ISO 11980:2012 Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations.

Expected drop-out rates for both the Test and the Control lenses are calculated to be approximately 15%.

Due to the limited sample sizes required for this study the power calculations and level of significance are not appropriate for calculation. Differences between the results for the Test and Control cohorts will be evaluated based on clinical judgments.

8.3 Analysis & Procedures

Throughout the analysis of data, the results for each patient/eye will be used when available for summarization and analysis. All subject data will be considered for evaluation unless a significant protocol deviation was reported. Written justification will be required for the use of data in the evaluation of the safety and/or efficacy of study product from any subject or investigational site found to have a significant protocol deviation.

Summary analysis for all dispensed subjects will be presented, including completed and discontinued subsets of the Test and Control populations.

Descriptive statistics will be reported by cohort at baseline, fitting and follow-up. Continuous variables will be summarized using sample size (N), mean, standard deviation (SD), minimum and maximum, and categorical data variables will be summarized using the sample size, frequency distribution (count and percentage of subjects or eyes in each category), mean and standard deviation.

8.4 Primary Safety Endpoint

The primary safety endpoints will be a comparison of the slit lamp findings and adverse events reported as associated with the Test lenses with those same findings reported as associated with the Control lenses by all scheduled and unscheduled follow-up visits. Slit lamp findings [redacted] are the primary indicators of safety issues with contact lenses.

[redacted]

Analysis of the results of the study will be based on a comparison of the differences in rates and degree of slit lamp findings between the Test and the Control lenses and the application of a clinical significance determination against the results. Clinical significance will be established through the average severity of the findings reported.

It is expected that the frequency and severity of the slit lamp findings and adverse events will be substantially equivalent between the Test and the Control lenses.

The following slit lamp findings will be presented and the frequency and average severity of findings by visit will be assessed.

- Epithelial Edema
- Stromal Edema
- Corneal Infiltrates
- Corneal Vascularization
- Corneal Staining
- Limbal Hyperemia
- Bulbar Hyperemia
- Palpebral Conjunctivitis
- Other Slit Lamp Findings

[redacted]

8.5 Primary Efficacy Endpoint

The primary efficacy endpoint in this evaluation will be a comparison of the reported Snellen distance visual acuities as associated with the Test and Control lenses during scheduled visits. It is expected that the lens Snellen distance visual acuity results will be substantially equivalent between the Test and the Control lenses.

The visual acuity measurements will be recorded using a standard Snellen VA chart calibrated for an effective visual distance of 20 feet.

The visual acuity measurements will be analyzed using the relative comparative distribution of the visual acuity reports across the Test and Control lens groups.

In addition, the lens visual acuity at the final study visit will be compared to the over refractive lens visual acuity at the Training-Dispensing visit and the changes (≥2 line change) assessed and compared across the Test and the Control Lens groups. It is expected that the results of both analysis will be substantially equivalent between the Test and the Control Lenses.

[redacted]

8.7 Additional Statistical Consideration

8.7.1 Interim Analysis

There will not be any interim analysis for this study.

8.7.2 Study Completion or Termination

The trial will be considered completed when all subjects have exited from the study as completed or discontinued.

The trial may be terminated if one or more of the following conditions are present:

- The IRB or the Sponsor determines that the trial should be terminated due to the identification of a safety issue.
- The Sponsor determines that the study results indicate a failure of the test device to meet the efficacy criteria set forth in this protocol.

If the trial is terminated, all active subjects will be brought in for a close out examination, the investigational product and supplies will be collected and the subjects discontinued from the study.

8.7.3 Procedures for Reporting Deviations from the Statistical Plan

Protocol deviations will be tracked and evaluated for possible effects on the study outcomes analysis. Deviations determined to create questionable or problematic data will be identified and the specific data excluded from the analysis.

8.7.4 Specifications of Subgroups for Analysis

There are no specific subgroup analyses planned for this study data.

8.7.5 Procedures for Accounting for All Data

The study report will include all data presented in summary tables or detailed listings. A visit accounting table will identify missed visits by cohort (Invigor A or Invigor B) and Status (Completed or Discontinued).

8.7.6 Treatment of Missing, Unused or Spurious Data

The analysis set will be the full analysis set, which consists of all subjects randomized into the study with an actual lens dispensed. Discontinued subject data will be analyzed separately from the completed subject data.

Missing data will be accounted for in the sample size accounting.

8.7.7 Justification for Excluding Data from the Testing of the Hypothesis

Protocol deviations determined to create questionable or problematic data will be identified and the specific data excluded from the analysis. Any data excluded from the study analysis will be identified and a written justification filed.

8.7.8 Minimum/Maximum Number of Subjects at Each Investigational Site

Each investigational site is expected to enroll a minimum of 12 subjects and at Sponsor and FRS's request may enroll up to a maximum of 24 subjects.

8.7.9 Factors Which May Compromise Outcomes or Interpretation of Results

The factors which may compromise the outcomes of the study or the interpretation of the study results are:

- Too few subjects, either Test Lens (<50 subjects) or Control Lens (<25 subjects), who fail to complete the 91 day time point.
- Loss of an investigational site.
- Significant protocol deviations by subjects or investigational sites.
- Each of the above items could have a significant effect on the data to be evaluated, thereby making analysis problematical.

9 DATA MANAGEMENT

9.1 Procedures for Data Review, Data Cleaning, Issuing and Resolving Queries

The procedures for data review, database cleaning and query management are all specified in the Data Management Plan on file [redacted].

[redacted]

9.3 Data Archiving

The procedures for archiving of documents and data files are all specified in the Data Management Plan [redacted].

9.4 Retention Period

The sponsor, [redacted] and the principal investigators shall maintain the clinical investigation documents as required by the applicable regulatory requirement(s). They shall take measures to prevent accidental or premature destruction of these documents. [redacted] the principal investigators or sponsor may transfer custody of records to another person/party and document the transfer at the investigational site or at the sponsor's facility.

All study records as listed below will be maintained by the investigational site for a minimum period of **three years following formal written notification** by the Sponsor or designee that the device has been approved for marketing or that the study has been withdrawn from the approval process.

1. A copy of the signed Statement of Investigator.
2. A copy of the approved Protocol and Protocol Signature document, including any revisions.
3. A copy of the approved Informed Consent Document used for this study.
4. Copies of the signed Informed Consent Documents for each subject enrolled into the study.
5. Copies (electronic or hardcopy) of all completed Case Report Forms for each subject enrolled into the study.
6. Copies of all records relating to adverse events, including but not limited to culture reports, records and reports from outside practitioners, healthcare facilities and laboratories.
7. All records of investigational product accountability (shipping, receipt, return, disposition and reconciliation forms).
8. A copy of Institutional Review Board approval and all correspondence.
9. All correspondence records (written, electronic and oral) related to this study.
10. The Statement of Financial Disclosure for the Principal and all Sub-Investigators.
11. All other documents required by State or National agencies.

Sites that use the CRFs as source documents must retain copies of the visit information as patient records for the time that is appropriate for their individual state requirements, even following notification from the Sponsor that the other documentation for the study may be destroyed.

9.5 Other Aspects of Quality Assurance

[redacted] ndividual sites will be monitored and quality issues identified and addressed.

10 CLINICAL INVESTIGATIONAL PLAN DEVIATIONS

10.1 Licensed Investigator Management of Protocol Deviations

A protocol deviation which has not been pre-approved, by the IRB and meets any one of the following criteria will be considered Significant if the deviation

- Affects the rights, safety and welfare of the study subjects
- Changes the risk/benefit ratio
- Affects the scientific design of the study
- Violates any ethical principle

Significant deviation must be reported to the IRB and FRS within ten (10) working days of a licensed investigator's discovery of significant deviation.

Loss of inventory control is also considered a significant protocol deviation and must be reported to FRS within 5 working days of an study coordinator or licensed investigator's discovery of the deviation.

10.2 Corrective and Preventative Actions and Investigator Disqualification Criteria

Should an investigator be found to be non-compliant with the study protocol and procedures, the Study Monitor, [redacted] and/or the Sponsor will provide a correction plan. If the investigator is found to be unwilling or unable to convert non-compliant practices, it is the Sponsor's obligation to terminate that investigator's role in the investigation and notify the IRB.

11 ETHICS, STANDARDS, AND REGULATORY

11.1 Statement of Compliance

This clinical study has been designed in conformance with the United States Federal Guidelines, the ethical principles in the Declaration of Helsinki, with the principles of US and ISO Good Clinical Practice (GCP), and with the references listed below:

- Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses (May 1994)
- 21 CFR Part 812 Investigational Device Exemptions
- Declaration of Helsinki
- ISO 11980:2012 Ophthalmic optics – Contact lenses and contact lens care products – Guidance for clinical investigations.
- ISO 14155:2011 Clinical investigation of medical devices for human subjects: Clinical investigation plans.

11.2 IRB Approval and Requirements

Approval of the study protocol and informed consent document must be obtained from an appropriate legally constituted Institutional Review Board (IRB) before investigational materials can be released and the study initiated. Renewal of this approval must be obtained as required by the IRB, but not less than annually.

The IRB must be informed of all serious, significant and unanticipated Adverse Events within 5 working days or as stated in the IRB approval letter. The IRB must approve all modifications to the protocol, the Informed Consent Document, or subject surveys prior to the changes being implemented. In addition, advertisements for subject recruitment must be approved by the IRB and Sponsor prior to dissemination or use.

A final report of investigational site's study results must be submitted to the Sponsor and the IRB by the site's principal investigator within 3 months of completion or termination of the study along with other reports as required in the study design and by the IRB. (21CFR812.150(a)6)

11.3 Confidentiality Statement

This study is confidential in nature. All information gathered during this study is proprietary and should be made available only to those individuals directly involved in the study who have a "need to know".

Authorized recipients of this data include:

1. Principal Investigator(s) and Sub-Investigator(s)
2. Other allied health care personnel under direction of the Principal Investigator(s) or Sub-Investigator(s) necessary for the conduct of the study
3. Institutional Review Board personnel
4. Employees of the Sponsor who have been identified as being authorized to receive or have access to study information.
5. Designated Study Monitor(s)
6. FDA or other government regulatory agencies

All above personnel who are provided with data concerning this study will be informed of its confidential and proprietary nature.

Release of this data (through presentation, publication or other written or oral communication) to other than the above listed personnel requires the **prior** written permission from the Sponsor Study Director. Study investigators and all office personnel are prohibited from acknowledging participation in the study to individuals and organizations except those listed above. This includes sales representatives and other departments and/or subsidiaries of the parent company of the Sponsor without direct written permission of the Sponsor.

11.4 Monitoring and Audits

The investigator will allow the study monitor(s) and auditors from Foresight Regulatory Strategies, Inc., Sponsor representatives and/or IRB members to observe procedures and inspect study records and subjects' medical records throughout the study to verify protocol compliance, case report completeness and investigational material accountability.

11.5 Investigator Responsibility

The principal investigator is responsible for following the clinical investigational plan (also referred to as the clinical protocol) as presented

herein, including protocol compliance, adverse event and protocol deviation reporting, maintaining documentation and control over the study investigational products and supplies, attending to subject safety, oversight of sub-investigators and investigational site staff, and communications with [redacted] the IRB, study monitor and Sponsor.

If the investigator's reviewing IRB withdraws approval for the investigator's part of the study, this must be reported [redacted] within 5 working days. Discontinuation of the study subjects will be completed at the direction of the IRB and in consultation with [redacted] the study Sponsor.

Interim study reports must be provided by the principal investigator to the IRB at a frequency required by the individual IRB, but not less than annually.

A IRB final report must be completed by the principal investigator and a copy provided to the Sponsor, [redacted] and the IRB upon completion of the study.

11.6 Statement of Insurance to be Provided to the Study Subjects

The informed consent document will contain a statement of insurance in regards to coverage of adverse events to the study subjects.

12 PUBLICATION POLICY

Each investigational site participating in the study may not report on the study results in their site until the study has been completed and all data verified. The Sponsor reserves the right to review and comment on any presentation, publication or other written or oral communication prior to publication or presentation.