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

STUDY TITLE: A Phase 2, Double-Masked, Randomized, Placebo-Controlled, Dose-Response Study Assessing the Safety and Ocular Hypotensive Efficacy of Two Concentrations of SBI-100 Ophthalmic Emulsion in Patients with Elevated Intraocular Pressure

PROTOCOL NO: SBI-100-201

STUDY DOCTOR: <First Name> <Middle Name> <Last Name>, <Suffix>

STUDY SITE: <Company Name>
<Address>
<City, State, ZIP>

TELEPHONE: <Telephone>
<Telephone #2, if applicable>

SPONSOR: Skye Bioscience, Inc.

You are being asked to participate in a medical research study. Your participation is voluntary, meaning that you can decide if you want to take part. For you to make this decision, you are being provided with this informed consent form (ICF). This ICF will describe the purpose, procedures, risks, and possible benefits of the study and explains how your medical information will be used and who may see it. This is provided so that you can make an informed decision about participating. This process is known as informed consent. You may have a copy of this form to review at your own pace or to ask advice from others.

Please read this ICF carefully, it may have words you do not understand. The study doctor and study staff can answer any questions you may have and explain words or information that you do not understand. After reading the ICF, you can ask the study doctor/staff any questions you have. If you would like to participate, you will be asked to sign this form. You cannot participate in this study without first having signed this form. You will be given a signed copy of your ICF to take home and keep for your records.

Skye Bioscience, Inc. (Skye) is the sponsor paying for this research study. The sponsor is the company that is developing the study drug.

BACKGROUND

You are being asked to take part in this research study because a doctor has noted that you have elevated intraocular pressure and you are at least 18 years of age.

Having elevated intraocular pressure (IOP) can put you at risk for glaucoma. Glaucoma is one of the most common eye diseases that affects vision. It is estimated that 60 million people worldwide

have glaucoma, with up to 3 million in the United States. If not treated, glaucoma can lead to worsening vision loss and blindness. Glaucoma does not have a lot of symptoms, but the first sign is usually elevated IOP. Elevated IOP can cause loss of sight at the edges of your vision, and higher levels of elevated IOP can cause optic nerve (how your eye communicates with your brain) damage, leading to blindness. There are many treatments available to help reduce IOP and prevent loss of vision.

PURPOSE

The purpose of this research study is to assess the safety and efficacy (how well the drug works) of two dose levels of SBI-100 Ophthalmic Emulsion (0.5% and 1.0%) compared to placebo in patients with elevated IOP.

This study involves the use of an investigational drug called SBI-100 Ophthalmic Emulsion (the study drug); that is being developed to help decrease IOP. An investigational drug is a drug that has not yet been approved by the U.S. Food and Drug Administration (FDA) but may be used in research studies like this one, to test to see if it is safe and effective.

SBI-100 is an eye drop that contains synthetic (manmade chemical) Tetrahydrocannabinol (THC). THC comes from the cannabis sativa plant and is known as marijuana or cannabis.

Studies have shown inhaling (smoking) or ingesting (eating) THC lowers IOP. This lasts for a short time and comes with other side effects. As an eye drop, SBI-100 could deliver THC directly to the tissue that drains eye fluids and controls IOP (trabecular meshwork). This method of delivering THC may help drainage, which may lower IOP for longer than smoking or eating THC and come with less side effects.

The results of this study may help the study doctor and sponsor better understand how SBI-100 works in lowering IOP and if it is safe for use. This may lead to future FDA approval in treating elevated IOP.

STUDY DESIGN & DURATION

Around 54 people (men and women) age 18 and older at up to 6 clinic sites across the U.S. will participate in this study. Should you choose to sign this ICF, your participation in the study will begin today. If you are eligible at today's visit, you will return to the clinic for 3-4 additional visits. If you are currently taking drugs to lower your IOP, you will be asked to stop using them and wait up to 35 days before using the study drug. Your last visit will take place about 8 days after you begin using the study drug. Your participation in this study from start to finish will be as short as 9 days and as long as 44 days. Your study doctor can tell you how long you will likely be in the study based on your current medications.

This is a placebo-controlled, randomized, double-masked study.

Placebo-controlled

A placebo is a substance that does not have active drug or provide any therapeutic benefit. In a placebo-controlled study, some participants receive placebo and others receive the active study drug. In this study, the placebo is an eyedrop that is identical to SBI-100 but will not contain any THC.

In this document, you may see the terms “treatment” and “treatment period.” These are terms used in research studies and do not mean that you will be receiving medical treatment for any condition. The term “treatment” applies to any study drug (active SBI-100 or placebo), and “treatment period” applies to the period of time during which you will use the study drug.

Randomized

A computer system will randomly assign (like the flip of a coin) each participant to receive one of two dose levels of the study drug or placebo. It will keep track of which group each participant was assigned to. The process of randomly assigning participants to a treatment group is known as Randomization, and studies using this process are considered randomized.

In this study, about 18 participants will be assigned to each of the three treatment groups. This means you will have about a 66% chance of receiving active study drug and about a 33% chance of receiving the placebo.

Double-masked

Should you choose to participate, you, your study doctor and study staff will not know what treatment group you are assigned to, or if you have received the active study drug or placebo. These types of studies are referred to as double-masked, as both you and the study doctor/staff do not know the treatment assigned.

Although participants assigned to receive placebo may not benefit from participation, the use of placebos, randomization, and double-masking in clinical trials prevents bias in collecting and reviewing the study data.

Your study doctor will be closely monitoring your health and safety during the study. Your study doctor will be allowed to know which treatment you are receiving if it becomes necessary for medical reasons. Your study doctor can also prescribe additional (non-study) drugs for your treatment, if needed.

PROCEDURES

The following tests and procedures will be performed during the study, either to determine if you are eligible to take part in this study and/or to measure the safety and effectiveness of SBI-100. These tests may be performed several times during the study, as outlined in the “Study Visits” section of this document.

- **Informed Consent:** this ICF will be reviewed with you and your questions will be answered by the study doctor/staff. If you decide to participate in the study, this ICF must be signed before any study-related procedures are performed. This will occur at your first visit and can happen again if there are changes made to the study that could affect your willingness to continue participation.
- **Eligibility Review:** your health history, medication history, study visit findings, and other relevant information will be reviewed to determine if you are eligible to participate in the study.
- **Record Demographic Information:** information about your age, race, ethnicity, and sex.
- **Record Health and Medication History:** the study staff will discuss and collect detailed information about your:
  - Medical history, eye related history, past or current conditions, procedures, surgeries and within the last 6 months.
  - Medications (prescription, over the counter, or supplements) that you are currently taking or have taken in the last 30 days.
  - Social history including smoking (nicotine), recreational alcohol and drug use within the last 12 months.
- **Vital Signs:** your breathing rate, heartbeat counts, and blood pressure will be recorded.
- **Females:** will be assessed for childbearing potential.
  - If you are a female who can become pregnant, you will be tested for pregnancy before starting the study and it must be negative for you to participate. You will also be tested at the end of the study. You must prevent pregnancy throughout the study by using an effective method for birth control.
  - If you are post-menopausal (no menstrual cycle for at least 12 months) or surgically sterile (had a hysterectomy, bilateral oophorectomy or bilateral salpingectomy at least 6 months ago), you are considered of non-child-bearing potential. You do not have to have a pregnancy test performed or use a method of birth control.
- **Drug and Alcohol Testing:** you will be asked for urine and/or a saliva sample to test for alcohol and drugs, which includes tests for THC.
  - If you currently use marijuana or products that contain THC or CBD, you cannot participate in this study.
  - If you test positive for drugs that require a prescription, the study doctor will need to confirm this and determine if you should participate.
- **Safety Lab Testing:** about 2 teaspoons of blood will be drawn and a urine sample will be collected for laboratory tests.
- **Ocular (Eye) Exams:** may be performed on one eye or both eyes as needed, based on the visit requirements and the study doctor's opinion. At some visits, these tests will be performed multiple times.
  - **Manifest Refraction** – a series of lenses will be placed in front of your eyes, and you will be asked questions to help find the best lenses to correct your distance vision (for example, "Which is better, 1 or 2?").
  - **Vision Exam –** using the best lenses to correct your distance vision, you will be asked to read letters on a chart.
  - **Pupil Measurements** – a handheld device will measure your eye's pupil diameter and their reaction to the lighting conditions.
  - **IOP Test** – measures the pressure on the surface of your eye. A numbing drop and bright yellow dye will be dropped into each eye to make the test more comfortable. You will be

asked to stare at a fixed point while the measuring instrument is gently placed on your eye for a moment.
  - **Eye Exam –** a light will be used to look into your eyes, at your eyes and eyelids with a microscope to assess their overall health and any changes since your last visit.
  - **Eye Exam with Dilation** – a light will be used to look at your eyes, eyelids and into your eyes, with both a microscope and magnifying lenses to assess their health and any changes since the last exam. Special drops will be used to dilate your pupils (make them open). Dilation allows the study doctor to see more of your eye and parts that cannot be seen when your pupils are their normal size.
  - **Ocular Comfort Assessment** – you will be asked questions about how your eyes feel at the time.
  - **Measuring Corneal Thickness** – a hand-held device will measure the thickness of the thinnest part of your cornea. A numbing drop will be placed into each eye to make the test more comfortable.
  - **Visual Field Test –** measures all areas of your eyesight, including your side, or peripheral (outer), vision. You will be asked to look inside a bowl-shaped instrument called a perimeter and press a button each time you see a flash. This test will be performed on both eyes. If you have had a visual field test within 3 months prior to the Screening Visit, you may not be required to repeat the test at the Screening Visit.
- **Study Drug Dosing (On-Site):** during visit days, the study staff will administer the study drug. The study staff will provide at home dosing instructions prior to giving you the study drug.
- **Study Drug at Home Dosing:** you will perform dosing at home starting with the evening dose on Day 1. On Days 2 through 6, you will dose at home twice a day.

STUDY VISITS

The schedule of required study visits and the procedures (described above) that will be performed at each visit are outlined in this section. In addition to these visits, your study doctor may ask to see you for additional "Unscheduled Visits" at any time they feel it is necessary to properly assess your safety.

Visit 1 (Screening Visit) *(2 to 35 days before use of study drug)*

- Informed Consent
- Labs
  - Safety lab testing (blood and urine)
  - Pregnancy test (blood), for women of childbearing potential
  - Drug and alcohol testing
- Record Demographic Information, Health History & Medications
- Review Childbearing Potential & Birth Control Methods
- Eye Exams
  - Manifest Refraction
  - Vision Assessment
  - Pupil Diameter
  - IOP Test
  - Eye Exam with Dilation
- Vital Signs

- Measuring Corneal Thickness
- Visual Field
- Eligibility Review

Visit 2 *(1 day before use of study drug)*

- Eligibility review and record changes (if any) in health and medication history
- Record (if there are changes) Health History, Medications
- Urine Pregnancy Test, for women of childbearing potential
- Drug/Alcohol Test (urine and saliva)
- IOP Test: around 8:00AM, 10:00 AM and 4:00PM

Visit 3 – Day 1 *(First day of Study drug use)*

- Eligibility review and record changes (if any) in health and medication history
- Procedures before dosing:
  - Vital signs
  - Vision assessment and pupil measurement
  - Eye exam without dilation
  - Ocular Comfort Assessment
  - IOP test
- Study drug administered by study staff around 8:00 AM
- Procedures after dosing will occur around the following times:
  - Eye exam without dilation: 15 minutes and 2 hours.
  - IOP test: 15 min, 2 hours and 8 hours.
  - Vision assessment and pupil measurement: 2 hours.
  - Ocular Comfort Assessment: immediately after dosing up to 2 minutes, 5 minutes and 10 minutes. If your eye comfort is not the same as it was before the dose, this will be repeated as needed.
- Study staff will provide you instructions on how to perform at home dosing and give you the study drug.

Visit 4 – Day 7 *(7 days after first dose of Study drug)*

- Record changes (if any) in health and medication history
- Procedures before dosing:
  - Vital signs
  - Vision assessment and pupil measurement
  - Eye exam without dilation
  - Ocular Comfort Assessment
  - IOP test
- Study drug administered by study staff around 8:00 AM
- Procedures after dosing will occur around the following times:
  - Eye exam without dilation: 15 minutes and 2 hours.
  - IOP test: 15 min, 2 hours and 8 hours.
  - Vision assessment and pupil measurement: 2 hours.

  - Ocular Comfort Assessment: immediately after dosing up to 2 minutes, 5 minutes and 10 minutes. If your eye comfort is not the same as it was before the dose, this will be repeated as needed.
- Study drug return: you must bring all used and un-used study drug; the staff will review at home dosing with you.

End of Study Visit – Day 7, 8, or 9 *(7-9 days after first dose of Study drug)*

- Vision assessment and pupil measurement
- Eye Exam with Dilation
- Eye Pressure Test
- Measure Corneal Thickness
- Vital Signs
- Visual Field
- Safety Laboratory Assessments
- Urine Pregnancy Test, for women of childbearing potential
- Collect a urine sample to test for THC

YOUR RESPONSIBILITIES

It is important that you follow the study doctor's instructions during the study. If you have questions or want further information, contact your study doctor, or study staff.

Health

Throughout the study, it is important that you inform your study doctor of any changes in your health, whether or not you think they are related to the study drug. This is so your records can be updated, and your study doctor can determine if it safe and appropriate for you to continue in the study.

Study Restrictions:

- If you use contact lenses, you cannot wear them 7 days before your next visit and throughout the study.
- Do not use lubricating eye drops, scrubs, or ointments within 15 minutes before or after dosing the study drug at home.
- Do not use lubricating eye drops, scrubs, or ointments during study visits.
- Do not use any form of marijuana or cannabis. This includes products that contain THC or CBD throughout the study.
- You cannot have a planned eye surgery or procedure during this study.

Study Drug Administration and Storage:

- On Days 2 through 6, you will put 1 drop in each eye in the morning around 8:00AM and in the evening about 12 hours after your morning dose (about 8:00PM).
- After using a vial, you will place it back into the pouch. **DO NOT** throw away the vial after use.

- You will store the treatment in a refrigerator and make sure it does not freeze and that it is kept out of the reach of children. During transport, the vials should be protected from extreme temperatures and placed into the refrigerator immediately.
- Keep track of missed doses and reasons for missing, the study staff will review this with you at your next visit.
- Do not instill the study drug the morning of your next visit to the clinic. It will be administered by the study staff during the visit.
- Make sure all vials (used and un-used) are returned for the Day 7 visit.

Drugs/Medications

You must tell the study doctor about all drugs/medications you are currently taking. This includes medications prescribed by your regular doctor and medications that do not require a prescription (for example, from a pharmacy or health food shop), including herbal medications, vitamins, and supplements. The study doctor will let you know if you can continue taking these. You must tell the study doctor before making changes to your current medications or taking any new medication.

Study Visits

Your study doctor/staff will schedule your visits based on the study needs, which were created to monitor your safety and properly collect information for the study. During the study, it is important that you attend each study visit and try not to reschedule your visits. Delaying or missing a visit could affect your safety or make the data for the study unusable. If you cannot attend a study visit at the scheduled time, you must contact your study doctor's office right away to reschedule the visit as soon as possible.

RISKS AND DISCOMFORTS

With any new study drug, there is always a chance of developing problems from the treatment. Your participation in this study involves risks from using the study drug and from having procedures performed as a part of this study. Not all risks or problems from using the study drug are known. You should tell your study doctor or the study staff about any changes to your health or any side effects that may occur while taking part in this study.

If you are assigned to receive the active study drug, it may or may not be effective in treating your elevated IOP. If you are assigned to receive the placebo, you will not receive any active treatment for elevated IOP. In either group, you may experience increased elevations of IOP. Your study doctor will closely monitor your safety during the study. If you experience any eye pain, severe headaches, or other concerning symptoms between visits, it is important that you contact your study doctor/staff. If needed, your study doctor can prescribe FDA-approved medications to treat your elevated IOP to ensure your safety.

If other medications are needed to treat your elevated IOP, your study doctor will prescribe the required treatment and ask you to stop using the study drug. You may be asked to come to the clinic for an extra visit to assess your safety and you will be asked to continue to return for your scheduled study visits so your health and safety can be monitored.

Risks Associated with THC

SBI-100 has not been studied in humans before and the effect it has on the human body is unknown. However, THC has been studied extensively in humans when it is either inhaled (smoked) or ingested (eaten). The common side effects include:

- Increased heart rate
- Coordination problems / slower reaction times
- Sleepiness (lethargy)
- Memory loss
- Increased anxiety and/or depression
- Dry mouth

As the study drug is new, the study may show additional side effects. However, the study drug has been tested in animals. Animal studies can predict what side effects may happen in people. The study drug was found to be well tolerated in different species of animals at various dose levels.

The amount of THC absorbed through the eye is expected to be very low. However, you should be careful when operating a vehicle or heavy machinery while taking the study drug.

Since the study drug contains THC, it is possible you could test positive for THC during workplace testing or drug screening. Think about your individual circumstances when deciding if you will take part in this study. This may be important if your employer has requirements for drug testing. You will be tested for THC at your final study visit. If the test is positive, your study doctor may decide to test you again.

Unforeseen Risks

In addition to the risks related to the use of THC, when using the study drug alone or in combination with other drugs, there may be other risks that are currently unknown. Long-term effects are not known at this time.

All drugs have the potential risk of causing an allergic reaction that, if not treated promptly, could become life threatening. As with any drug, it is possible that you could experience an allergic reaction to the study drug. Symptoms of any allergic reaction can include a rash, hives, itching, difficulty breathing, closing of the throat, swelling of the lips, tongue, or face, and (rarely) death.

If you have a known allergy to sesame seeds or sesame oil let your study doctor know and do not continue participation in the trial.

If you think you are having a severe allergic reaction, call 9-1-1 and seek medical attention immediately.

Pregnancy Risk

If you are a woman who can become pregnant, to reduce the risk of pregnancy, you must use an effective method of birth control while you are in this study. If you are already using a method of birth control, the study doctor/staff will discuss with you whether your current method of birth control is acceptable for use in this study. Acceptable methods of birth control include:

- Hormonal birth control (oral birth control pill, long-acting implantable hormones, injectable hormones)
- A vaginal ring or an intrauterine device (IUD)
- Tubal ligation (having your tubes tied)
- Male (sole) partner has had a vasectomy with follow-up confirming the absence of sperm

If you are male, your partner should use one of the birth control methods above while you are using the study drug. The acceptable method of male birth control include:

- Vasectomy with follow-up visits that confirmed the absence of sperm

It is not known whether the study drug affects pregnant women, unborn children, or children of nursing women. Because of these unknown risks, you may not enter the study if you are pregnant, breastfeeding, or trying to become pregnant. A pregnancy test will be done before you enroll in the study and when you exit the study. During the study, you should not attempt to become pregnant, and you should not breastfeed a child.

If you become pregnant during the study, you should notify the study doctor promptly. Your study doctor will discontinue the use of the study drug but your participation in this study will continue through Visit 5 so that your safety can be monitored. The study staff will contact you to ask about the outcome of your pregnancy.

POTENTIAL BENEFITS

You may benefit because of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Results from this study may benefit other patients with elevated IOP in the future.

ALTERNATIVE TREATMENTS

If you decide not to participate in the study, you can continue using your existing treatment for elevated IOP or your study doctor will discuss treatment options available to you and their important potential benefits and risks. Alternative treatments for ocular hypertension may include ophthalmic topical prostaglandin analogs (latanoprost), topical beta-blockers, and topical alpha-adrenergic agonists, or other drugs.

NEW INFORMATION

You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

COMPENSATION TO YOU

For your time and inconvenience related to your participation in this study, you will be paid for the study visits you complete according to the following schedule:

Visit 1 (Screening)	<Per Visit>
Visit 2 (Day -1)	<Per Visit>
Visit 3 (Day 1)	<Per Visit>
Visit 4 (Day 7)	<Per Visit>
Visit 5 (EOS)	<Per Visit>
Unscheduled	<Per Visit>

If for any reason, you cannot finish the study or the study is stopped early, you will be paid for the visits you complete. A completed visit means all scheduled study procedures have been performed.

Patients who do not qualify at the screening or randomization visit will be compensated <Per Visit>.

COSTS TO YOU

There will be no costs to you for taking part in this study. All study drug, tests, procedures, and visits that are part of this study are being paid for by the Sponsor and will be provided to you at no cost. The costs of standard medical care that are not part of this study will be billed to you and/or your insurance company in the usual way.

VOLUNTARY PARTICIPATION/WITHDRAWAL

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

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

- if it is deemed to be in the best interest of your health and welfare.
- if you fail to respond to the study drug.
- if your symptoms worsen or you have severe or unacceptable side effects.
- if you fail to follow instructions.
- If you become pregnant
- If you require a drug that is not allowed by the study

If these events occur after using the study drug, your study doctor may stop use of the study drug but ask you to return for the remaining study visits to monitor your health and well-being.

STUDY COMPLICATIONS AND COMPENSATION

The study doctor, study staff, and sponsor have taken steps to minimize the risks of this study. Please tell the doctor or staff if you have any injuries or problems because you entered the study. If you become sick or injured as a direct result of a properly performed study procedure or because you are taking the study drug as directed, appropriate medical care for the immediate treatment of the illness or injury will be given to you.

The Sponsor may reimburse reasonable out of pocket costs deemed medically necessary if you become injured or ill by participating in this study. You agree to cooperate in obtaining payments from insurance or other third-party coverage that may be available. No financial payments or other forms of compensation (such as lost wages, physical therapy or other recovery needs, other loss of income or pain or suffering or discomfort) have been set aside for such injuries; however, you do not waive any of your legal rights or release anyone from liability for negligence by signing this document.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE, AND DISCLOSE YOUR MEDICAL INFORMATION

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

The study drug will be kept in a secure location at the clinic and may be under video surveillance. Throughout the study, you may be recorded by these security cameras.

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

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

- Name
- Address
- Telephone number
- Birth date/Age
- Race
- Sex
- Allergies
- Drugs you take (current and past)
- Use of marijuana, opiates, methadone, cocaine, amphetamines, barbiturates, benzodiazepines, and alcohol.
- Information from the eye exams done by the study doctor
- Results of study tests and study procedures
- Other information from other doctors' offices, clinics, and/or hospitals that is needed for the study

Information collected about you for the study will be kept in a research file that is separate from your medical chart. You will not be able to see your research file until after the end of the study.

The study team will know your identity; however, your records will be labeled with a code that is randomly assigned to you. The research staff are the only people who will have this code and its key.

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

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

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

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

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

You have a right to see your study records; however, you will not be able to see your study records until after the study has ended.

You may also take away (or withdraw) your permission for the use of your PHI at any time. If you choose to withdraw your permission, you must write your study doctor a letter.

The study doctor's mailing address is <Company Name>, <Address>, <City, State, ZIP>. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your

medical care and your relationship with the health care providers at the study center will not be affected.

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

QUESTIONS

If you have questions, concerns, or complaints about the research study or you experience a research-related injury, please contact Dr. <Last Name> or the study staff at <Telephone> or <Telephone #2, if applicable>.

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

PARTICIPANT STATEMENT AND AUTHORIZATION

I have read this Participant Informed Consent Form and Authorization to Use and Disclose Medical Information, which is printed in English. This is a language that I read and understand. I agree to participate voluntarily in this study. I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.

I will receive a signed copy of this form.

All my questions have been answered.

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

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date