INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Main Study Title:	**Kodiak Sciences Inc. / "A Multicenter Platform Study on the Safety, Tolerability, Bioactivity, and Pharmacokinetics of Intravitreal Therapies in Retinal Vascular and Inflammatory Diseases"**
Substudy Title:	**"A Randomized, Double-masked, Sham-controlled, Multicenter, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal Tabirafusp Alfa (KSI-101) in Participants with Macular Edema Secondary to Inflammation (MESI) – PEAK/PINNACLE"**
Main Protocol Number:	**KSMP001**
Substudy Protocol Numbers:	**KSMP001-S1 (PEAK)** **KSMP002-S2 (PINNACLE)**
Principal Investigator: (Study Doctor)	**Eric Chin, MD**
Telephone:	**(909) 335-8940 (24 Hours)**
Study Site:	**Retina Consultants of Southern Ca** **1895 Orange Tree Lane** **Suite 204** **Redlands, CA 92374**

KEY INFORMATION

You are invited to take part in a research study. The research is studying an investigational drug called KSI-101 as a possible treatment for vision loss due to macular edema, or swelling of the light-sensitive tissue at the back of the eye (the retina), secondary to (caused by) inflammation. Investigational means it is a drug

being tested and has not yet been approved by the regulatory authorities, such as the U.S. Food and Drug Administration (FDA). You are being asked to participate in this research because you have been diagnosed with macular edema secondary to inflammation (MESI).

This research involves two studies (PEAK and PINNACLE). If you decide to participate and are eligible for the research, your Study Doctor will put you in one study or the other, depending on the level of swelling and vision you have as part of your MESI diagnosis. The procedures that will be completed and the study treatments being evaluated for each study are the same. Both studies are covered in this consent form. In this document, the term “study” or “research study” applies to both studies.

Kodiak Sciences Inc. (hereafter referred to as Kodiak) is sponsoring this research. Kodiak will manage and pay for this study, and the Study Doctor is paid by Kodiak to conduct this study.

This form describes the study and your role as a possible participant. Please read this form carefully. Take your time to ask the Study Doctor or study staff as many questions about the study as you would like. The Study Doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the Study Doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form. You will receive a copy of the signed and dated form.

Your participation in this research study is voluntary, meaning that you can choose if you want to take part in the study. You can leave the study at any time, without any reason. Doing so will not change your health care or your rights. If you do not want to join the study, you can talk to the Study Doctor about your health care.

The purpose of this research study is to evaluate the safety, tolerability, and effectiveness of the investigational drug, KSI-101, compared to sham (pretend) treatment. Your participation in this study will last approximately 52 weeks, and will include laboratory assessments, examinations and photographs of your eyes, and eye injections (or sham injections).

Taking part in this study may or may not help to treat your MESI. If KSI-101 is effective, your vision may improve. If you receive sham as part of this study, your MESI may not improve or may get worse. It is possible that you may not personally benefit from your participation in this study. However, by taking part, you will provide new information that may benefit other people in the future.

You may have side effects from the study treatments or procedures used in this study. Side effects can vary from mild to very serious and may vary from person to person. Everyone taking part in the study will be watched carefully for any side effects.

There may be reasons why you would decide not to participate in the study. The Study Doctor will ask you about your health and your family history. This information, along with the results of screening tests, will help the Study Doctor decide if you will be eligible for the study. If you are not an appropriate candidate for this study, the Study Doctor (who may or may not be your ophthalmologist) will discuss your future options with you and may refer you back to your ophthalmologist or primary care doctor (if applicable).

An Institutional Review Board (IRB) has reviewed this study to make sure that your rights and welfare are protected after you join this study. This committee will watch over this study while you are participating in it.

BACKGROUND AND PURPOSE

For MESI, the standard treatment is currently corticosteroids (a type of drug used to reduce inflammation in the body) administered as eyedrops, an injection locally (injections in or around the eye), or administered systemically (tablets taken orally or as intravenous injections). Although corticosteroids are the standard treatment for MESI, some patients continue to have disease or vision loss despite this treatment. Use of corticosteroids also comes with risks such as early development of cataracts (clouding of the clear lens inside the eye), and glaucoma (permanent damage to the nerve in the eye due to increased pressure inside of the eye).

It is believed that certain proteins in the eye are involved in causing macular edema. One of these proteins is called vascular endothelial growth factor (VEGF). When there is too much VEGF inside the eye, swelling, or macular edema, can occur, which may result in vision loss. Another one of these proteins is called Interleukin-6 (IL-6). Kodiak has designed a study drug, KSI-101, which blocks both VEGF and IL-6. By blocking both proteins, KSI-101 may further improve the treatment of MESI.

The purpose of this research study is to:

- Learn if KSI-101 is safe and tolerable compared to sham (pretend) treatment.
- Learn if KSI-101 is effective in improving vision compared to sham treatment.
- Evaluate how KSI-101 affects your blood and the fluid in your eye over time after the investigational drug has been given.

KSI-101 has been tested in people and in animals and has been shown to be safe and well tolerated so far.

In this document, you may see the terms “treatment” and “treatment period”. These are terms used in research studies and these terms do not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this study drug. This form may refer to KSI-101 or sham as “study drug” or “study treatment”.

It is expected that approximately 150 adults (both men and women) aged 18 and older, will take part in each study worldwide, for a total of approximately 300 participants.

WHAT WILL HAPPEN DURING THE STUDY?

Your involvement in this study will last approximately 52 weeks and will include approximately 15 study visits to the study center. There will be a screening period of approximately 4 weeks, a 44-week study treatment period, and a 4-week follow-up period with a final visit occurring at Week 48.

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. There will be several screening examinations, tests, and procedures that you will undergo to find out if you are eligible for the study. If you are not familiar with any of the study assessments, please ask your Study Doctor to explain how they are performed. If your screening results indicate that you are eligible to continue in this study, you will be asked to come back to the study site on Day 1 for study dosing.

If you qualify to take part in this study and go on to receive the study treatment, you will be randomly assigned (by chance, like the flip of a coin) to receive either 5mg of KSI-101, 10mg of KSI-101, or sham study treatment. Your chance of receiving 5mg of KSI-101 is 33% (1 in 3), your chance of receiving 10mg of KSI-101 is 33% (1 in 3), and your chance of receiving sham study treatment is 33% (1 in 3).

This study is double-masked, which means that neither you nor the masked Study Doctor nor study staff will know what study treatment you are receiving. An exception to this is the unmasked Study Doctor who administers the study treatment; he or she is informed about your study treatment but will not share this information with you or the masked study team.

If you are assigned to the 5mg of KSI-101 or 10mg of KSI-101 study treatment group, you will receive the study treatment by injection into one of your eyes, called the study eye, by an ophthalmologist (a medical doctor specializing in the treatment of eyes). If both of your eyes are affected, the eye with the better potential for improvement in vision, as determined by the Study Doctor, will be the study eye. If both eyes have the same potential, the right eye will be designated the study eye. Before the KSI-101 injection is given, eye drops or an injection will be used to numb your eye, and your eyelids and eye will be disinfected. If you are assigned to the sham treatment group, your eye will still be made numb and disinfected in preparation for an injection, but instead of an actual injection of study drug into your eye, a small amount of pressure will be applied to your eye using a blunt syringe (with no needle), to pretend that you are receiving an injection. Because your eye will be numb, you will not know if you received an actual or sham injection.

You will receive up to 12 injections (or sham injections) during the 44-week study treatment period of the study. You will receive an injection (or sham injection) on Day 1, at Week 4, Week 8, Week 12, Week 16, and Week 20. Then, you will continue to visit the study center every month and you will be treated with your assigned study treatment group and receive injections (or sham injections) depending on how your MESI is doing as shown by your eye examinations, until Week 44.

If you are discontinued from the study for any reason, or if you decide to end your participation after receiving study dosing, you may be asked to undergo Early Termination (ET) assessments (for additional information, please see section on "What will happen at the end of the study or if you stop your participation early?" below).

The following assessments will be performed during the study:

- **Demographics:** During the Screening Visit, the Study Doctor will ask questions about you, including your age and sex at birth. You will be asked about your race and ethnicity (for clinical research purposes only). This is because we do not know whether the effects of the study drug are influenced by race or ethnicity.

- **Medical, Ocular, and Medication History:** During the Screening Visit, you will be asked about your medical history and, if you do not object, your Study Doctor may need to contact and obtain previous medical history or data from your other treating physician(s). This is done for your safety. You will also be asked about any prescription or non-prescription drugs, herbal treatments, or nutritional supplements that you are taking or planning to take. A full eye history, including any prior eye treatments, will also be noted. At all other visits, you will be asked about any changes to the medicines you have been taking, asked how you have been feeling since you were last asked, and if you have noticed any health changes or events.

- **Vital Signs:** Your heart rate, blood pressure, and body temperature will be measured at Screening, Day 1, and the Week 48 or ET visit. Your height and weight will be measured at Screening only.

- **Pregnancy Test:** If you are a woman capable of becoming pregnant, you will need to provide a urine sample for a pregnancy test at Screening, Day 1, and at each visit thereafter (except for Week 1). If your urine test is positive, your blood will also be tested to confirm whether or not you are pregnant.

- **Blood Samples:** At the Screening visit and the Week 48 or ET visit, blood samples (about 2 teaspoons or 9 mL per visit) will be collected for routine safety laboratory tests, to check your blood cell counts, protein levels and to check your liver and kidney function. At Screening, an additional blood sample (about 1 teaspoon or 5 mL) will be collected to test for Syphilis. The study doctor may be required by law to report the result of these tests to the local health authority.

- **Plasma Samples for Immunogenicity Assessment:** At Day 1, Week 24, and the Week 48 or ET visit, additional blood samples (about 1 teaspoon or 4 mL per visit) will be taken to test for the presence of antibodies for the study drug. This is to understand potential immune responses that may also affect your response to KSI-101.

- **Plasma Samples for Pharmacokinetic (PK) and Biomarker Testing:** At Day 1, Week 1, Week 4, Week 24, Week 28, and the Week 48 or ET visit, additional blood samples (about 1 teaspoon or 4 mL) will be taken to test for PK (which measures how the study drug moves through the body) and biomarkers (a measurable indicator of the severity or presence of some disease state). At these visits, the concentration levels of KSI-101 in your blood will be tested to see how your body is processing the study drug. The levels of naturally occurring substances, or protein biomarkers, in your blood will also be measured to see if your response to KSI-101 is affected by these proteins in your blood.

- **Aqueous Samples for PK and Biomarker Testing:** If you elect to participate in aqueous sampling, a small amount (approximately 2 drops) of fluid will be collected from your eye using a very fine needle at Day 1, Week 4, Week 24, Week 28, and the Week 48 or ET visit. Eye drops or a numbing injection may be used so that you do not feel pain. This sample will be used to test the amount of study drug in your aqueous humor, the clear fluid in the front of your eye. This is called ocular pharmacokinetic testing and could provide useful

information regarding how long the study drug lasts in the eye and how levels of study drug inside the eye relate to vision.

- **Best Corrected Visual Acuity:** This is measured in both eyes at Screening and at the Week 48 or ET visit, and only in the study eye at all other visits. The sharpness of your vision will be measured by your ability to identify letters or numbers on an eye chart.

- **Eye Examinations:** are conducted in both eyes at Screening and at the Week 48 or ET visit, and only in the study eye at all other visits.
  - A Slit-lamp examination will include an examination of your eyelids, the surface of your eye, and the inside of your eye including the pupils, iris, lens, and retina.
  - Eye pressure will be measured using a tonometer, a device that briefly touches the surface of your numbed eye to measure the pressure inside.
  - The retina will be examined more closely using an ophthalmoscope. For this test, you will be given eye drops to dilate the pupil to examine the back of your eye.

- **Specular Microscopy:** may be conducted in both eyes at Day 1, Week 24, and the Week 48 or ET visit, if your Study Doctor has the required equipment. A special camera is used to take a picture of and measure/count the cells of your cornea (front of the eye).

- **Optical Coherence Tomography (OCT):** is measured in both eyes at Screening and the Week 48 or ET visit, and only in the study eye at all other visits. OCT uses invisible light rays to take a picture of the back of your eyes and is done to measure the thickness of your retina.

- **Fundus Photography:** is conducted in both eyes at Screening and the Week 48 or ET visit, and only in the study eye at Week 24. A special camera is used to take color photos of the back of your eye. Additional photographs may be taken at other visits if the Study Doctor feels it is necessary.

- **Fluorescein Angiography:** is conducted in both eyes at Screening, Week 24, and the Week 48 or ET visit. This test involves first injecting a dye into a vein in your arm and then taking photos of the back of your eye. These photos help to

get a better look at the blood vessels and other structures in the back of the eye.

- **Post-injection Assessment:** After every injection (KSI-101 or sham injection), there will be a vision check and eye pressure will be measured for the study eye. You will be asked to stay in the clinic for approximately an hour after each injection to confirm that you are tolerating the injection well. If you are doing well after the injection, you may be able to leave sooner, or the Study Doctor may ask you to stay longer if further observation is needed after your injection.

The Study Doctor may want you to come into the clinic for visits at times not otherwise described above, for example, if you are having a problem after receiving your study drug injection and/or need to be seen sooner or more often. This is referred to as an Unscheduled Visit. The assessments performed at Unscheduled Visit(s) are at the discretion of the Study Doctor.

BIOLOGICAL SAMPLES

The number of scheduled times blood samples will be drawn during the study is 7 times. The volume of blood that will be taken each time will vary from 4 mL (about 1 teaspoon) to about 17 mL (about 1 tablespoon). The total amount of blood drawn in this study for participants will be about 59 mL (about 4 tablespoons).

The number of scheduled times aqueous samples, if you decide to participate in this sampling, will be taken during the study is 5 times. The total amount of fluid that will be collected from you will be approximately 10 drops over the entire duration of the study

If you change your mind later, be aware that your samples may or may not be withdrawn from the research, depending on the Sponsor's policies. You can ask the Study Doctor or study staff about this.

Your blood and aqueous samples may be sent for testing to Cenetron Diagnostics, LLC for safety testing, and to PPD Laboratories (Richmond, VA) or Kodiak Sciences Inc. (Palo Alto, CA) for immunogenicity, PK, or biomarker testing. In addition, some of your blood samples may be tested at a local laboratory in the event the

central lab cannot process your blood quickly enough (for example, to determine if you are eligible to participate in the study or in an emergency). Samples will be identified by a code and will not show who you are.

Samples that are not immediately analyzed will be kept for a maximum of 5 years, with the exception of samples for biomarker testing which may be stored for up to 15 years, following the last participant's last visit of the study or the time that is required to complete the study, publish the data related to the study, and support any regulatory applications for the study drug, whichever is longer. Your samples will then be destroyed. You have a right to be informed of any plans for new analyses on retained identifiable samples that are not currently foreseen, and you have the right to refuse further analyses.

Any remaining immunogenicity, PK and/or biomarker samples not already used for testing in the study may be used for optional exploratory research. The research would be to evaluate the levels of VEGF, IL-6, and other factors in the samples to help researchers learn more about the disease. You are free to refuse to participate in this optional exploratory research for any reason, and this will not influence your participation in the study. Should you consent to participate in the optional exploratory research, you may withdraw your consent at any time during the storage period.

The samples you provide will not be used for genetic or DNA testing.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Keep your study appointments. If you cannot keep an appointment, contact your Study Doctor or study staff to reschedule as soon as you know that you will miss the appointment.
- Tell your Study Doctor or study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell your Study Doctor or research study staff if you experience pain or discomfort during any of the procedures required by this research study.
- While participating in this research study, you are not allowed to take certain treatments that may affect your study eye. You must alert your Study Doctor before taking any new medication during the research study. This is to protect you from possible harm that may result from combining

medications.

- While participating in this research study, you should not take part in any other research study. This is to protect you from possible injury arising from such things as extra blood draws, the possible incompatibility between research drugs, and other similar hazards.
- Ask questions as you think of them.
- Tell your Study Doctor or research study staff if you change your mind about staying in the study.
- If you are female and capable of becoming pregnant, you should take precautions to avoid pregnancy. If you become pregnant, tell your Study Doctor as soon as you know (for additional information, please see section on "birth control restrictions" below).

WHAT WILL HAPPEN AT THE END OF THE STUDY OR IF YOU STOP YOUR PARTICIPATION EARLY?

After the study drug is stopped, your Study Doctor will discuss your future options with you and may refer you back to your ophthalmologist or primary care doctor (if applicable). Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

If you have withdrawn from the study before its conclusion, your Study Doctor (or appointed delegate) may ask you to complete an Early Termination (ET) visit. If you fail to return for final assessments, one of the study site personnel may contact you by phone for a follow-up. This is done to have complete data about your health and safety at the end of the study. If you leave the study, there will be no penalty, and you will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care you are given.

The Study Doctor or Sponsor may stop the study drug or end your participation in this study at any time without your consent for any of the following reasons:

- Staying on study drug or in the study would be harmful for you.
- If the study drug has caused any side effects to you.
- You need treatment that is not allowed in this study.
- You did not follow instructions about what to do in the study.
- If it is discovered that you do not meet the study requirements.
- The study is cancelled, or your study treatment group is stopped.
- If you are a woman of childbearing potential and become pregnant.

- For administrative reasons.

The Study Doctor will tell you the reason(s) why you should stop being in the study.

If you have experienced any side effects, you may be followed up until it is resolved. If not resolved, you may be followed for a period of not more than 3 months. During this time your Study Doctor (or appointed delegate) may try to find out your long-term health status by continuing to access your medical records or if needed, by searching publicly available sources such as national registries, newspaper obituaries, and social networking websites. Attempts may also be made to contact you or your relatives to collect this information. If you do not want this information about you to be collected, let your Study Doctor know at any time.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Possible risks from receiving the study treatment KSI-101:
KSI-101 may not improve your vision. Your vision and the damage to the back of your eye may get worse. For example, large studies of eye injections that block VEGF have suggested approximately 5 to 10% of participants may be expected to lose 15 or more letters (3 lines on the visual acuity chart) over time, regardless of the specific anti-VEGF medicine used.

Some people taking other standard eye injections that block VEGF have had heart attack, stroke, or death. It is not known if the eye injections caused these problems. Tell your Study Doctor if you have had a heart attack or stroke in the past. Whether KSI-101 has a higher, lower, or the same potential risk of heart attack or stroke as other anti-VEGFs is not known at this time.

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Signs or symptoms of a life-threatening allergic reaction (anaphylaxis) include:

- Severe eye inflammation, with eye pain, sensitivity to light, or redness
- Rash
- Fast pulse
- Sweating

- Feeling of dread
- Swelling around the eyes and mouth
- Swelling of the throat
- Wheezing
- Having a hard time breathing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Inability to breathe without assistance

You should get medical help and contact the Study Doctor or study staff if you have any of these or any other side effects during the study.

The study drug might have other side effects, including serious ones, which are not known at this time. Such side effects cannot always be predicted.

Any important new information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you, and you may be asked to sign and date an updated consent document.

Possible risks from receiving eye injections:
Eye injections can cause other eye problems. Known very common side effects, or side effects observed in more than 10% of participants receiving eye injections with approved anti-VEGF drugs, include the following:

- Bleeding under the skin of the eye – the white part of your eye might turn bright red. This is from a small amount of bleeding on the surface of your eye and due to the eye injection procedure. It will not change how well you see and will usually clear up in about a week.
- Eye irritation and pain – your eye may feel irritated or painful and make a lot of tears for a few hours.
- Cataracts (clouding of the eye's lens).
- Vitreous detachment (separation of the gel like substance in the middle of the eye from the retina – light-sensitive tissue at the back part of the eye).
- Increased eye pressure.
- Feeling that something is in your eye.
- Floaters (spots in your vision) – you might see small specks or floaters. Many people already have floaters. These new floaters may go away in a few days, or you may stop noticing them.

Known common side effects, or side effects observed in less than 10% of participants have included the following:

- Eye inflammation – the inside of your eye can become irritated and inflamed due to the injection procedure or due to the study drug.
- Damage to the retina – the retina can become torn or detached due to the eye injection. If you see a curtain over your vision or part of your vision becomes missing, you should let your Study Doctor know right away.
- Damage to the cornea or other structures of the eye.
- Bleeding within the eye.
- An infection inside the eye. This happens rarely with any injection inside the eye but can be serious.

Some of these complications are rare, yet may lead to severe, permanent loss of vision.

The following are possible risks from the study procedures:

<u>Injection Preparation</u>
Prior to performing the study injection (or sham injection), your Study Doctor or delegate will disinfect your study eye and eyelids and will numb the surface of your eye. This may result in temporary irritation, burning, or itching of the eye or eyelids.

<u>Blood Tests</u>
When a sample of your blood is taken, you may experience some temporary discomfort, bruising, swelling, and/or, in rare circumstances, infection at the needle site. You may feel dizzy, or you may feel faint. There is also a small risk of nerve damage at the place where the needle is inserted, which can be permanent in rare cases.

<u>Aqueous Samples</u>
When a sample of your aqueous is taken, you may experience side effects including:

- Low eye pressure
- Watery eyes and redness
- Eye infection

- Cataracts (clouding of the eye's lens)
- Eye inflammation

Eye Examination

In order to improve the view of the inside of your eyes during the eye examination, your pupils will be dilated using eye drops. Dilation of the pupil may cause light sensitivity and slight blurring of vision for approximately 4 hours after the examination. Wearing sunglasses while your pupils are dilated can help reduce the discomfort of light sensitivity. Driving may be difficult, and it is better to have someone take you home. On the day of the visit, you should refrain from driving and operating machinery.

Fluorescein Angiogram

After the yellow dye (fluorescein) is injected into a vein in your arm or hand, your skin may turn yellow for several hours. The yellow color will disappear as your kidneys remove the dye from your body. Because the dye passes through your kidneys, your urine will turn dark orange for up to 24 hours after the procedure. You may have an upset stomach during the procedure, but this usually lasts only a few seconds. If the dye leaks out of your vein during the injection, some of the skin around the injection site may feel uncomfortable or become yellow. The discomfort usually lasts a few minutes, and the yellow color goes away in a few days.

Also, injection of the fluorescein dye may cause pain at the site of the injection and carry a risk of bleeding, bruising, and/or infection at the puncture site.

An allergic reaction to fluorescein is rare. If this does happen, you may have a rash or experience itching of your skin. A severe allergic reaction occurs very rarely (fewer than 1 in 1 million people) and may involve breathing and/or heart rhythm problems, which can be life-threatening. The Study Doctor will monitor you closely after the dye is injected and you may need to stay at the clinic for a little while afterwards to check that you are okay.

Ask the Study Doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

UNFORESEEN RISKS

Since the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot participate in this study.

For females, if you are capable of becoming pregnant and are having sex with a man, you must use an acceptable method of birth control (see below) during the entire study and for at least 90 days after the last study drug injection. During the study, if you think that you might be pregnant, you should tell your Study Doctor right away, as your participation in the study must be stopped. Data and information about your pregnancy, delivery, and newborn (if applicable) will be collected, up until about 6-8 weeks after your estimated delivery date. Pregnancies occurring up to 3 months after the last dose of the study drug must also be reported to the Study Doctor. The Study Doctor may arrange for you to be counselled by a specialist, to discuss the risks of continuing with the pregnancy and the possible effects on the unborn child. Monitoring of your pregnancy will continue until the outcome is known. One parent or legal guardian of the newborn (if applicable) may be asked to provide permission related to data collection for the minor.

Birth control methods with a failure rate of less than 1% per year are considered acceptable for this study and include the following:

- Bilateral tubal ligation (tubes tied, surgically sterilized)
- Oral birth control (when properly used)
- Birth control patch
- Long-acting injectable birth control (hormonal implants)
- Partner vasectomy (male sterilization)
- Intrauterine device
- Sexual abstinence (if in accordance with your normal lifestyle)

Birth control methods that have a failure rate of 1% or more are not acceptable and include a cap, diaphragm, or sponge with spermicide, or a male or female condom with or without spermicide. You must discuss with the Study Doctor the type of birth control method that you use, and the Study Doctor must approve that method before you can enter the study.

For males, there are no birth control requirements.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your MESI**.** Your other options may include:

- Corticosteroids
- Other types of eye injections

Your Study Doctor will explain the risks and benefits of other treatments. Please talk to the Study Doctor about your options before you decide whether or not you will take part in this study.

COSTS AND COMPENSATION FOR PARTICIPATION

Are there any costs if you decide to take part in the study?

Taking part in this study will not cost you anything. The study drug will be made available to you at no charge, and you will not be required to pay for any study procedures. You or your insurance company may be billed for any standard medical care that is not required for the research study.

Will you receive any payment if you take part in the study?

You will receive payment for participation in this study. You will receive $100.00 USD (United States Dollars) per completed in-office visit. If you elect to participate in the aqueous sampling, you will receive an additional $50.00 USD per sample collected at applicable visits. If you do not complete the study, you will be compensated for the visits you do complete. A completed visit means all scheduled study procedures have been carried out.

You will be paid following each completed visit.

You may be eligible for prepaid transportation to and from your study visits. If you decide not to use the prepaid car services, you may be eligible for other travel reimbursement to and from your study visits. Reimbursement of your travel expenses will be performed directly by your study site and receipts may be requested.

If you have any questions regarding your compensation or transportation needs for participation, please contact the study staff.

Will you receive compensation for injury resulting from the study?
It is important that you take care to follow all the instructions given by the Study Doctor and study staff about this study. You should inform the Study Doctor as soon as you feel that you have had an illness or injury related to the study, so that you can get proper health care. If you are injured because of your participation in this study, you will be entitled to receive compensation according to the local law. Your Study Doctor will explain more about this to you.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the Sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. Treatment for the injury will be made available through the Study Doctor and the study site. You are not waiving any legal rights by signing and dating this form, accepting medical care, or accepting payment for medical expenses.

To pay medical expenses, Kodiak will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the Sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

CONFIDENTIALITY

What will happen to your data?

This research study may be performed only by collecting and using your personal information. Your study records will be kept as confidential as possible, except as necessary to conduct or support this study and as otherwise described in this document. For information shared beyond the study site, only a number will be used to identify you. You will not be personally identified in any reports or publications that may result from this research study. Because of the research goals of this study, however, your study records cannot be kept completely confidential.

The study staff, the Sponsor, and its agents will need to review the medical information collected from you for use in this study to accurately record information for this study. In addition, to review the study findings, the US Food and Drug Administration (FDA) and other regulatory agencies may review your medical records.

The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing and dating this form, you are authorizing such access. If you do not sign and date this form to authorize access, you will not be able to participate in this research study.

The medical information that will be collected from you if you participate in the study includes the following:

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical and ocular history, vital signs, blood and urine tests, visual acuity, eye examinations, OCT, fundus photography, and fluorescein angiography.
- Information that is created or collected from you during your participation in the study, including the results of the tests for eligibility and any other procedures and tests performed during the study.
- Information contained in your medical records that is related to your medical history and treatment.

The medical information may contain your name, address, telephone number, Social Security Number, health plan number, study number, date of birth, dates of various medical procedures, and other personally identifying information.

If you sign and date this form and participate in the study, the study staff will be authorized to use the information described above for the purposes of the study. The study staff will also be authorized to provide access to or disclose the relevant information described above to the following parties involved in the study:

- Kodiak or other agents designated by Kodiak to collect or review study data for verification of study procedures and/or side effect reporting.
- Other employees or students of Kodiak or its authorized agents, who may accompany study monitors and auditors for quality and training purposes.
- The Institutional Review Board (IRB) that oversees the research study at your study site.
- Government regulatory agencies, including the FDA.
- Other parties and officials, as required by law, court order, or other legal mandate.

Once your information is disclosed to the Sponsor, its agents, the IRB, or government agencies as described above, it is possible that your medical information will be re-disclosed. In addition to disclosures to the entities identified above, your coded health information may also be disclosed to others involved in the research study, such as the following:

- Laboratories or offsite testing facilities for clinical tests required by study plans.
- Approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- Kodiak who directs the medical research studies.
- Other third parties contracted by Kodiak to provide services related to studies.

The study data may be transferred to other countries for processing, including countries that are not covered by data protection legislation. Kodiak, the Sponsor, is based in the United States.

While the study is in progress, your access to your study records may be limited. In order to protect the scientific integrity of the study, the study treatment you receive in this study needs to remain unknown (for example, masked) until the study data are analyzed.

You may have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study staff and other entities.

Study data, including your coded medical information, may be used and shared for pharmaceutical research purposes related to this study. This authorization has no expiration date, except for study sites located in California (CA), Minnesota (MN), and Illinois (IL), where the authorization expires 50 years from the date signed.

The Sponsor has contracted vendors, who will know your real identity, although they will only be informed about your medical condition, if necessary, to perform the services being provided.

To ensure your privacy, your name and other directly identifying information will not be attached to records or samples released for research purposes. Only the Study Doctor and authorized personnel will be able to connect this code to your name. Your coded data will be forwarded to Kodiak and its service providers for activities related to the study (for example, laboratory analysis). The data will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported or published. If the results of the study are published, your identity will remain confidential.

Under federal data protection law, the Health Insurance Portability and Accountability Act (HIPAA), and specific regional regulations, your study site shall be responsible for ensuring that your information is safeguarded. You have the right to access, through your Study Doctor, all the information collected about you and, if applicable, to ask for corrections. Recipients of your information may be in countries that do not have data protection safeguards and rights. Kodiak, its authorized representatives, and regulatory authorities shall, in all cases, seek to maintain confidentiality within the limits of local laws.

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.

This Web site only shows data in English, but you can request information from the study staff at any time and have access to data that are publicly available.

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

What if you change your mind and do not want your data to be used or disclosed?

You may withdraw your authorization at any time by sending a written request to the Study Doctor listed on the first page of this form. If you withdraw your authorization, data collected prior to your withdrawal may still be processed and stored along with other data collected as part of the study. Normally, no new information will be collected for the study database unless you specifically consent to it. However, the law does require that any side effects that you experience are documented and reported. To complete the study findings, your long-term health status may also be obtained from public sources. You have the right to require that any previously retained samples are destroyed.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Print Full Name of Participant

_____ _____

Signature of Participant Date

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ (if applicable)

The study participant has indicated that he/she is unable to read. The Authorization has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____

Print Full Name of Impartial Witness (if applicable)

_____ _____

Signature of Impartial Witness Date

COMMERCIAL PROFIT

The study Sponsor, Kodiak, has plans to develop commercial products using the information obtained from this study and your study results. You will not be compensated for any commercial use or other use of this information, nor will you have any financial or proprietary interest in any products or processes that may result from research on your study results.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Study Doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Study Doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00087644.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

STATEMENT OF CONSENT

- I have read and understand the information in this informed consent document.
- I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction.
- I voluntarily agree to participate in the study until I decide otherwise.
- I do not give up any of my legal rights by signing this consent document.
- I understand that I will receive a copy of this signed and dated consent document.

Do you agree to allow the study site to notify your family doctor or primary healthcare provider of your participation in this study and/or any significant findings related to your health?

_____ Initial	Yes, I agree for my family doctor or primary healthcare provider to be notified by the study site of my participation in this study and/or any significant findings related to my health.
_____ Initial	No, I do not agree for my family doctor or primary healthcare provider to be notified by the study site of my participation in this study and/or any significant findings related to my health.

Kodiak would like to obtain aqueous samples from your eye. This is an optional part of the study, and you can choose whether to participate in it or not. If you are not willing to have aqueous samples taken from your eye, you can still participate in the study. Do you agree to participate in the optional aqueous sampling for this study?

_____ Initial	Yes, I agree to participate in the optional aqueous sampling and allow my study doctor to take aqueous samples from my eye.
_____ Initial	No, I do not agree to participate in the optional aqueous sampling and allow my study doctor to take aqueous samples from my eye.

Kodiak would like you to allow them to use any remaining blood or aqueous samples for optional exploratory research that may help understand more about MESI. This is an optional part of the study, and you can choose whether to participate in it or not. Do you agree to allow your blood and aqueous samples to be used for exploratory research related to MESI?

_____ Initial	Yes, I agree for my blood or aqueous samples to be used for exploratory research related to MESI.
_____ Initial	No, I do not agree for my blood or aqueous samples to be used for exploratory research related to MESI.

_____

Print Full Name of Participant

_____ _____

Signature of Participant Date

- I have presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated Informed Consent Form.

_____

Print Full Name of Person Obtaining Consent (Study Doctor/Delegate)

_____ _____

Signature of Person Obtaining Consent Date

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ (if applicable)

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____

Print Full Name of Impartial Witness (if applicable)

_____ _____

Signature of Impartial Witness Date