INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

PHASE-1/2 (PART 1B)

Sponsor / Study Title:	**Kalaris Therapeutics, Inc. / "A PHASE 1/2 CLINICAL TRIAL TO ESTABLISH THE SAFETY, TOLERABILITY, DOSE RANGE, AND PHARMACOKINETIC PROFILE OF INTRAVITREAL INJECTION OF TH103 IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (nAMD), AND A DOSE-FINDING, MASKED, COMPARATIVE SAFETY AND PRELIMINARY EFFICACY STUDY OF TH103 IN PATIENTS WITH nAMD, DIABETIC MACULAR EDEMA (DME) AND RETINAL VEIN OCCLUSION (RVO)"**
Protocol Number:	**KLRS-100**
Principal Investigator: (Study Doctor)	**John Carlson, MD**
Telephone:	**909-335-8940 (24 Hour)**
Address:	**Retina Consultants of Southern Ca** **1895 Orange Tree Lane** **Suite 204** **Redlands, CA 92374**

You are invited to participate in a research study. This informed consent form (ICF) tells you about this study. Please read this ICF with care and ask the study doctor or study staff all your questions. When you understand what is in this ICF, you will be asked to sign and date it to join this study. You will receive a copy of the signed and dated ICF.

Taking part in this study is voluntary. This means 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.

Kalaris Therapeutics, Inc. (called Kalaris after this) is the study drug company, as well as the Sponsor that will run and pay for this study. The study doctor is also paid by Kalaris to run this study.

Advarra is an Institutional Review Board (IRB) and 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.

INFORMATION ABOUT THIS STUDY

Why is this study being done?

We have asked you to join this study because you have neovascular age related macular degeneration, or wet AMD (called nAMD after this). There are 3 parts to this study: Part 1a, Part 1b and Part 2. You are only being asked to participate in **Part 1b** of the study.

Approximately 140 subjects will participate in this study overall. Approximately 30 adults will take part in Part 1b of this study at 20 to 40 clinical study sites in the United States (US). Additional participants might be added to the study at the Sponsor's discretion.

The study will test an investigational study drug called TH103, which is a new drug that is being developed for treating people like you with nAMD. "Investigational" means that it is not yet approved by any health authorities or regulatory agency, such as the US Food and Drug Administration (FDA) for treating any condition, and it can only be used in a study like this. TH103 belongs to a group of drugs known as vascular endothelial growth factor (called VEGF after this) inhibitors, also called an anti-VEGF drug. TH103 is a new anti-VEGF drug that may be able to stop (inhibit) the growth of new blood vessels in the eye. Because of the way this study drug was created, it may work better and may last longer than currently available anti-VEGF therapies.

The goals of this study are to find a safe and effective multiple dose for people with nAMD and to find out how long it stays in your body and how your body gets rid of TH103 at different doses (this is called pharmacokinetics or PK testing). Kalaris wants to find out what effects TH103 has on people in this study.

From this point on, any references to the word "study drug" will mean TH103.

Study Design

To find the highest and safest multiple dose, subjects in Part 1b will receive four injections approximately one (1) month apart using a safe dose as determined in Part 1a of the study.

You will receive four intravitreal (inside the eye) injections of the study drug approximately one month apart. Between Months 5 through 8, if you meet specific criteria, you may receive treatment with a currently approved anti-VEGF treatment, which is the standard of care (SOC) treatment for people with AMD. The SOC drug and dosing will be discussed with you, and the study doctor will tell you more. Once you receive SOC, your participation in this study will end.

This is an open-label study. This means that you, the study doctor, study staff, and Kalaris will know the dose of the study drug you are receiving.

What will happen during the study?

If you are eligible (fit) to take part in Part 1b of the study, you will be in the study for at least 9.5 months and you will have to visit the study site about 16 times. This part of the study has 3 periods:

- Screening up to 14 days before dosing on Day 1.
- Four Study Treatments (Day 1, Month 1, Month 2 and Month 3) with follow-up visits one week after each study treatment. Four days after the first three study treatments (Day 1, Month 1, and Month 2), you will be contacted via phone. Four days after the fourth study treatment (Month 3), you will have a study visit to have your blood drawn.

Monthly Follow-Up from Months 4 through Month 9. After a study doctor reviews your eye disease, and if you receive SOC (starting Months 5 through 8) you will have your End of Study Visit on the same day that the SOC is given.

You will be asked to read, sign, and date this ICF before you have any study tests. If you want to take part in this study, your study doctor will first check to see if you are a good fit for this study. This part is called Screening and must be completed no more than 14 days before you get your first dose of the study drug. To take part in the study, you must have wet AMD which is an eye disease that is affecting your vision. It happens when tiny blood vessels grow in the wrong place in your eye and leak fluid.

The list below shows what will happen to you during the study. There is also a calendar of events after this list to show what happens at each visit. If you do not know these tests or want to know more, please ask your study doctor to explain.

- **Health history:** You will be asked about your health history, including your history of nAMD, and other eye treatments or eye surgery(s) to make sure you can join the study.
- **Current and previous medications:** You will be asked about the medications that you are taking or have taken before you take part in the study. At every visit you will be asked if there are any changes in your medications.
- **Questions about you:** You will be asked about your birth date, sex, race, and ethnicity.

- **Safety Phone Calls:** You will be called by phone to see how you are doing after certain treatments. The purpose of the call is to see if you are experiencing any new symptoms.
- **Eye exams:** You will have standard eye exams and scans (listed below) to check your vision and the health of the inside of your eye. For some of the tests you will have drops put in your eye, so that it is easier to see inside your eye. The tests will also check if there is enough blood flow in the eye.
    - Vision checks: You will be asked to read letters off 2 different types of charts to check how well you can see with and without glasses (if applicable).
    - Eye pressure checks: The pressure in your eyes will be checked after drops are put in your eye to numb them. You will not feel anything. For some of these tests a device on a stand will touch your eye briefly; for other tests a small device like a pen will touch your eye briefly to measure your eye pressure. Each eye will be tested separately.
    - Color fundus photography: You will look into a machine while it takes a picture of the back of your eyes called the fundus. Each eye will be tested separately.
    - Optical coherence tomography and optical coherence tomography angiography: A light source is used to examine your retina (back of your eye) and measure the thickness of your retina. You will be asked to sit in front of the machine, and a technician will ask you to look into a pattern of lights first with one eye, then with the other eye, while pictures are taken of your retina.
    - Fluorescein angiography: A small tube (called a cannula) will be placed into a vein in your hand or arm. A yellow dye called fluorescein will be injected into the cannula. This dye will travel through your blood to and into the blood vessels in your eyes. Photographs will be taken of your eyes as the dye passes through.

- **Vital signs:** Your vital signs, which include your blood pressure, heart rate, breathing rate, and temperature, will be measured.
- **Height and weight:** Height and weight will be measured
- **Side effect questions:** You will be asked about any changes to your health since your last visit.
- **Study drug injection**: TH103 is a clear solution and will be given as an intravitreal (inside the eye) injection. You will get the study drug in one eye on Day 1, Month 1, Month 2 and Month 3. Depending on your test results and the study doctor's judgement, you may be given treatment with standard of care (SOC) beginning at Month 5 through Month 8, at which time your study participation will end.
- **Physical exam:** You will have physical exams which include your general appearance, and checking your head, eyes, ears, nose, throat, heart, lungs, cranial nerves (nerves that send information between the brain and your eyes, ears, nose, and tongue), and abdomen. At other times, you may have a physical exam focused on any symptoms you may have.

- **Electrocardiogram (ECG):** You will have ECGs, which measure your heart's rhythm. Sticky patches will be placed on your chest, arms, and legs and connected by wires to the ECG machine for this test.
- **Urine tests:** You will be asked to collect urine samples for health checks.
- **Blood samples:** You will have blood collected from a vein in your hand or arm for the following tests:
  - For health checks such as counting the number of red and white blood cells and platelets (cells that help your blood clot) and to check your liver and kidneys.
  - For PK samples, to see how much of the study drug is in your blood.
  - For antidrug antibodies (proteins that help fight infections), also called an "immunogenicity" test. This is to see if your body makes antibodies to the study drug. If your body is making these antibodies, the study drug may not work as well for you.
  - If you can get pregnant, you will have a pregnancy test.
- **Unscheduled visits:** An extra visit may be performed if your study doctor feels additional time is needed to assess your side effects or medications.

The total amount of blood that will be collected from you during the study will be approximately 153 milliliters, or 32 teaspoons.

What happens to the samples collected from you?

Your blood samples for health checks will be sent to PPD Global Central Laboratory (2 Tesseneer Rd., Highland Heights, KY 41076) and to BioAgilytix Labs (2300 Englert Dr, Durham, NC 27713) to test if your immune system is reacting to the study drug (producing antibodies) and for PK testing. Your samples will be only identified by a code and will not show who you are. At any point during or after the study, you have the right to have your samples destroyed if you contact your study doctor. If you leave the study, your samples may not be destroyed immediately. All the samples and test data collected before you leave the study will still be used for study purposes.

What is expected from you?

While you are in the study, you must:

- Attend all study visits and if needed, reschedule appointments as soon as possible.
- Follow the instruction of the study staff.
- Undergo all the scheduled study assessments.
- Tell the study doctor about all medications that you are taking and check with the study doctor before taking any new medicines including prescription and over-the-counter medications, vitamins, and herbal supplements.
- Tell the study doctor about any new treatment or medication you take during the study.
- Give correct and complete information about your health history and current health.
- Tell the study doctor about any changes in your health during the study.

- If you get pregnant, or you get your partner pregnant, tell your study doctor as soon as you know (for additional information, please see section on “Are there any reproductive risks?” below).
- Agree to not post or discuss the study on social media.
- Be in touch with your study doctor or staff and tell them if you have a change in your contact information or if you no longer want to be in the study.
- Do not take part in any other study for 90 days before starting this study. You should also not take part in any other study while you are participating in this study.

Voluntary participation and withdrawal

Your participation in this study is voluntary. You may decide not to participate, or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. Your study doctor and/or Kalaris may learn new facts during the study that might make you want to leave the study and not get the study drug. You will be told about new facts in a timely manner. If you decide to leave the study, please tell the study doctor. 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 receive.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the Kalaris, the FDA, or other regulatory authorities. The study doctor will tell you the reason(s) why you should stop being in the study. Reasons you may be withdrawn from the study include the following: it is in your best interest to not be in the study, you need treatment not allowed in this study, you did not follow the study instructions, the study is stopped, or for other administrative reasons.

If you leave the study early, the study doctor will ask you to complete the end of study tests (such as a final health and eye exams and lab tests) for your own health. If you cannot see the study doctor in person, someone from the study staff will call you by phone. This is done to have complete data about your health and safety at the end of the study.

What will happen at the end of the study?

The study doctor will contact you when the study is close to the end. Your study doctor will also tell you if additional follow-up is needed and if you need to visit the study site again. You will not be able to get the study drug after the study is over. Your study doctor will discuss your future health care choices with you.

BENEFITS AND RISKS

Are there any possible benefits of being in the study?

Taking part in this study may or may not help to treat your nAMD. You will be watched closely for any changes to your vision, although your vision could improve, stay the same, or get worse. However, the data we get from you during this study may help doctors learn more about the study drug and nAMD and this may help future patients.

What are the potential risks and discomforts?

Risks of TH103

All drugs can cause effects that are not wanted. These are called side effects. This is the first time the study drug TH103 has been used in people. Tests in animals have shown the following side effects:

- Inflammation (swelling) of the eyes, including pain and redness
- Red eyes and eyelids
- Incomplete dilation of pupil (natural widening in dim environments to allow more light into the eye)
- Scarring of the front layer (cornea) of the eye
- Reduced fluid pressure inside the eye
- Blurry vision
- Decreased vision or loss of vision

The above findings are most likely due to injecting human protein into an animal eye. These findings are not expected to happen in the human eye since a human protein is being injected in the human eye and may not be considered foreign by the body.
If any of these side effects happen to you, tell your study doctor.

Additionally, mild ocular inflammation has been observed in a very small number of human subjects. This resolved in a couple of days with or without steroid eye drops.

Since the study drug has only been used in small number of people, there are side effects that are not yet known. If you notice any changes in your health, please tell your study doctor.

Risks of injection of study drug into the eye

The injection of any drug into the eye carries some risk. The risks are as follows:

- Bleeding from inside your eye or from small blood vessels on the surface of your eye (conjunctival hemorrhage)
- Infection
- Redness and swelling (inflammation)
- Tear or detachment of your retina, which occurs with any intraocular injection
- Pain at the injection site
- Eye irritation and a feeling that there is something in your eye

- Loss of an eye from a severe infection
- Increased intraocular pressure, which if long term and untreated may lead to optic nerve damage
- Temporary loss of vision
- Need for surgery to treat some of the complications noted above

You and your caregiver should report any pain, sensitivity to light, or disturbances in your vision to your study doctor immediately.

Risk of diagnostic tests

You may also have side effects from the tests you have during the study, such as the following:

- Blood collection: Collecting blood may cause bruising at the place where the needle goes into your skin. Fainting and, in rare cases, infection may happen.
- Blood pressure: The blood pressure cuff may cause discomfort or bruising to your upper arm.
- ECG: An ECG involves placing sticky patches on your skin. Your skin may become a little red or irritated if you have a response to the sticky material (adhesive) used.
- Fluorescein angiography: There is a small risk of having an allergic reaction to the dye injected as part of this test. The dye can also cause itching, rash, or a tingling feeling where the dye was injected. The most common reactions are brief episodes of nausea (feeling sick to your stomach) that happen in 3% to 15% of people, vomiting (throwing up) in 7% of people, and itching. More severe reactions such as a rash, fever, blood clot, and fainting are rare (fewer than 1 in 1,000 people). If the dye leaks out of the cannula, mild pain and redness may happen. It is common for the dye to make your urine and skin yellow which can last up to 48 hours. This is normal and will not cause you any harm. Drinking plenty of water will help flush it out.

Are there any reproductive risks?

Women who are **pregnant, breastfeeding, or planning to become pregnant** during the study will not be allowed to take part. Women who could get pregnant (not post-menopausal or surgically sterile) must have a pregnancy test to rule out pregnancy before they get the study drug. After joining the study, women must immediately tell the study staff if they think they are pregnant during the study.

Women able to get pregnant and who are having sex with any man must use 2 forms of highly effective birth control during the study. If you have not had a period for at least 12 months (you are postmenopausal) or you are surgically sterile, you don't need to use birth control for this study. Highly effective birth control is defined as:

- Tubal ligation (having your "tubes tied") or tubal occlusion (having your "tubes blocked")
- Approved hormonal contraceptive (birth control) such as oral contraceptives ("the pill"), contraceptive implants, injections, rings or hormonal intrauterine device
- Intrauterine devices: these are small birth control devices that are inserted into your uterus by a doctor or nurse to stop you from getting pregnant

These should then be used in combination with barrier contraception, such as condoms (external or internal), diaphragm, cervical cap, sponge, and vaginal spermicides.

You must discuss with the study doctor the types of birth control that you can use before you can participate in the study. The study doctor must approve the methods you use before you can enter the study.

If you become pregnant, the study doctor will advise you about your health care and will ask about your pregnancy and its outcome. The study doctor will ask if they may collect data on your pregnancy, its outcome, and information about your baby. If you agree to provide this information, you will do so only through your pregnancy and up to a maximum of 12 weeks after your estimated delivery date. If you or your unborn or newborn child has a health problem during this time, you must tell the study doctor, directly or through your baby's doctor or obstetrician/gynecologist, until the problem is solved or becomes stable.

You and your newborn child will not have any additional tests apart from those that your doctor or obstetrician/gynecologist normally does to monitor your pregnancy and the health of your unborn or newborn child. If the obstetrician/gynecologist believes that you and your unborn child need additional tests to make sure you are healthy, they will tell you. You have the right to agree to or refuse these additional tests. You will be asked to sign and date a separate ICF to allow collection of your pregnancy information.

If you are **male** and have sex with someone who can get pregnant, you must also use an external condom for the entire study. This is because it is not known if the study drug may affect your sperm or an unborn child.

Are there any other treatments?

Instead of taking part in this study, you may choose to receive standard treatment with approved anti-VEGF therapies. Your study doctor will explain the risks and benefits of these other treatments before you decide if you want to take part in this study.

COSTS AND COMPENSATION FOR STUDY PARTICIPATION

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

Taking part in this study will not cost you anything. You will not be charged for the study drug or any of the tests that are part of the study. Kalaris will not pay for doctor visits or other treatments or tests that are not part of this study. This means that you, your insurance company, or your government's health plan may have to pay for these treatments or tests that are considered a standard part of your care.

Your travel expenses to and from the study site may be paid for after you spend the money. Talk to your study doctor about any costs that might not be paid by Kalaris.

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

You will be paid $120 at the end of each completed visit.

You will not receive any payment for participating in the study, however, you will be reimbursed for study visit-related expenses (such as mileage, parking, meals, transportation) by Scout Clinical. You will be paid using ScoutPass, check, or bank transfer.

You may also have transportation arrangements to and from the study site provided for you and a caregiver (if necessary) by Scout Clinical for study-related visits.

To process reimbursements and prepare transportation arrangements for the study, Scout Clinical will collect information about you (and your caregiver, if necessary) that may include name, address, phone number, email address, study appointment dates, bank transfer instructions and your study subject ID code. National ID number or passport details may be collected to facilitate international travel if necessary. All information is stored in a secure fashion and will be deleted from Scout Clinical's system once the study has been completed. Scout Clinical will not share (disclose) your data to any third party unless in connection to one of these services and then only the specific data needed to provide the service will be shared.

Using Scout Clinical's services for visit-related reimbursement and transportation arrangement is not required for participation in the clinical study. If you wish to use Scout Clinical services as described above, please sign and date this ICF in the space provided. You may ask your study staff any questions you may have.

Please note, to protect your confidentiality Scout Clinical will use their internal Study Identification code of "S925" and also the PPD identification number of BC# 112214-01. If you are reaching out to Scout Clinical directly, please ensure to use these study identification numbers.

Tax Reporting
Reimbursements for participation in studies are considered taxable income. To comply with US tax laws, if you are participating in the study, you will need to provide a valid Tax Identification Number (TIN) or Social Security Number (SSN) to Scout Clinical. Personal information about you, such as your name, address, SSN or TIN may be provided to the Internal Revenue Service (IRS) and vendors working on behalf of Kalaris for tax purposes, and you may receive a tax form if you are reimbursed $600 or more in a calendar year.

If you do not provide a valid SSN or TIN, or if the SSN or TIN you provided does not exactly match the IRS records, Scout Clinical will withhold 33% of your reimbursement and send it to the IRS. This is called backup withholding and will continue until a valid SSN or TIN is provided.

Your study coordinator will provide all the necessary information about reimbursement. If you prefer not to be reimbursed for your travel expenses for this study, you may tell your study coordinator.

Will you receive compensation for injury resulting from the study?
Kalaris will make every effort to prevent any injury to you as a result of participating in this study. Signing and dating this ICF does not affect any of your legal rights.

Additional information may be obtained from your study doctor and/or the study staff.

You will get a card with information about the study drug and emergency contact information. You must carry the card with you as long as you are in the study and show it to anyone that may be involved in your health care.

If you have any changes in your health, unexpected symptoms, or injury, and emergency medical treatment is required, please tell your study doctor immediately, or call 911. If you are injured as a result of taking part in this study, you will be compensated according to local law.

What happens to the data collected about you?
The information below explains how your health records and the study data we get from the samples collected from you during the study may be used and shared with others. The study site will record basic personal details about you, including your name, contact details, sex, and race and ethnicity (to be used only for study purposes), as well as data on your health history and any study data collected about you. Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed.

The following people or groups may review your health records, to make sure that the study is being run as planned, and that the study data collected about you is correct:

- The US FDA
- The IRB
- Other individuals and organizations that analyze or use your information in connection with these research activities, contract research organization and study sites (if you transfer to another study site), contractors and consultants working with Kalaris, PPD, and the FDA.

All staff that can see (with access to) your medical records and study data are required to keep your information and study data private.

To ensure your privacy, you will only be identified by a code. Your name and other data that can identify you will not be attached to records or samples released to Kalaris and its service providers. Only the study doctor and allowed staff will be able to connect this code to your name with a list that will be kept safe by the study site for up to 2 years. Your birth date and initials may also be recorded to help identify your study records.

The photographs, images, and scans of your eyes will be stored at Duke Reading Center (2200 W. Main St., #220, Durham, NC 27705) and saved on servers managed by Duke Health Technology Solutions (2424 Erwin Road, Durham, NC 27715). Your information will be secured by password protected access to authorized users.

Kalaris, the study staff and the vendor will not use these images or scans for any other reason than those stated in this ICF without your written permission.

After your coded data are sent to Kalaris, the results of the study will be analyzed and reported. Kalaris may use your coded information to get the study drug approved for use in different countries.

The results may also be analyzed again at a later date or may be combined with the data of other studies. Kalaris and the people who work with them may use the results of this study to understand nAMD better, to review the safety or effectiveness of the study drug, or for other research purposes.

You have the right to see (access), correct, and limit access to your personal data at any time during the study. You can exercise these rights by telling the study doctor.

In this study, study monitors will be verifying certain data in-person as well as remotely without visiting the study sites.

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

If you leave the study early, data collected while you were in the study may still be kept with other data collected as part of the study. No new data will be collected for the study unless you clearly agree to it.

Will information about this study be 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 be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

CONTACTS

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 subject;
- 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00079571.

APPENDIX 1: CALENDAR OF EVENTS

The table below shows what happens at each visit. Your study doctor will explain to you each procedure and the tests to be performed at each visit. If you are not familiar with any of these tests, please ask your study doctor to explain how they are performed.

TESTS	SCREENING	DAY 1	DAY 4 (Phone call)	WEEK 1	MONTH 1	MONTH 1 +4 DAYS (Phone call)	MONTH 1 +7 DAYS	MONTH 2	MONTH 2 +4 DAYS (Phone call)	MONTH 2 [illegible]	MONTH 3	MONTH 3 + 4 DAYS	MONTH 3 + 7 DAYS	MONTH 4	MONTH 5	MONTH 6	MONTH 7	MONTH 8	MONTH 9/EW	UNSCHEDULED VISIT
Informed Consent	X																			
Questions About you	X																			
Health History	X	X																		
Physical Exam	X																		X	
Vital Signs	X																		X	
Eye Exams	X	X		X	X		X	X		X	X		X	X	X	X	X	X	X	X
ECG	X																		X	
Blood and Urine Tests for Health Checks	X											X							X	X
PK and Immunogenicity Tests		X		X	X		X	X		X	X	X	X	X	X	X	X	X	X	
Blood Pregnancy Test	X																		X	
Get TH103 Injection		X			X			X			X									
Get SOC Injection, After Disease Review															O	O	O	O		O
Safety Phone Call			X			X			X											
Side Effect Questions		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Current and Previous Medication Questions	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

O - Optional EW – Early Withdraw

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

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 ICF, you are authorizing such access. If you do not sign and date this ICF to authorize access, you will not be able to participate in this research study.

This research study may be performed only by collecting and using your medical information. Your study records will be kept as confidential as possible. Only a number and your initials 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 Sponsor of this study is Kalaris Therapeutics, Inc.

The study staff, the Sponsor, its agents, and PPD Investigator Services, LLC (“PPD”) (an organization that is contracted to help conduct the research) will need to review the medical information collected from you for use in this study in order to accurately record information for this study. In addition, in order to review the study findings, the US FDA, the IRB, and other regulatory agencies may review your medical records.

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

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical history, physical examination, vital signs measurements, ECG, blood, and urine tests.
- Information that is created or collected from you during your participation in the study, including the results of the ECG, blood and urine tests and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of

birth, dates relating to various medical procedures, and/or other identifying information.
If you sign and date this ICF and participate in the study, the study staff will be authorized to use the information described above to carry out the purposes of the research study. The study staff will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- Kalaris Therapeutics, Inc., PPD, or other agents designated by Kalaris Therapeutics, Inc. to collect or review study data for verification of study procedures and/or side effects reporting.
- Other employees of Kalaris Therapeutics, Inc., or its authorized agents, who may accompany study monitors and auditors for quality and training purposes.
- The IRB (Advarra) that oversees the research study at your site. Government regulatory agencies including the US FDA.
- Other research doctors and medical centers participating in this study.

The Sponsor has contracted the following vendors, which will know your real identity, although will only be informed about your medical condition if necessary to perform the service:

- Scout Clinical, a travel arrangement and reimbursement company

Once your information is disclosed to Kalaris Therapeutics, Inc., its agents, the IRB, or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by US federal privacy regulations. In addition to disclosures to the entities identified above, PPD may further electronically disclose your coded health information to others involved in the research study, such as:

- To laboratories or offsite testing facilities for clinical tests for safety and immune responses as required by study plans.
- To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- To Kalaris Therapeutics, Inc., who directs the research study.
- To other third parties contracted by PPD and/or Kalaris Therapeutics, Inc. to provide services related to the study.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.

While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research study is completed. You 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 subject to federal privacy regulation.

Study samples and data, including your coded medical information, will be sent to Kalaris Therapeutics, Inc., and used and shared for pharmaceutical research purposes related to this study and for future pharmaceutical research and development purposes. This authorization has no expiration date. In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign and date this authorization document.

In signing and dating this ICF, you authorize the use and disclosure of your information for purposes of the study at any time in the future. If you decide not to sign and date this ICF, you will not be able to take part in the study.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on the first page of this ICF. If you withdraw your authorization, data collected prior to your withdrawal may still be processed along with other data collected as part of the study.

Normally, no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects that you may 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 refuse to sign and date this authorization, which will result in your inability to participate in the study. You will receive a copy of this authorization after you have signed and dated it.

STATEMENT OF AUTHORIZATION

I have read this authorization, 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 authorization. I will receive a signed and dated copy of this authorization for my records. I am not giving up any of my legal rights by signing and dating this authorization.

_____

Printed Name of Subject, in full

_____

Signature of Subject Date (dd-Mmm-yyyy)

I have presented the authorization and answered the subject's questions. I will give the subject a copy of this signed and dated authorization.

_____

Printed Name of Person Obtaining Authorization (Study Doctor/Delegate)

_____

Signature of Person Obtaining Authorization (Study Doctor/Delegate) Date (dd-Mmm-yyyy)

STATEMENT OF CONSENT

- I have read and understand the statements in this ICF.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to take part in this study of my own free will.
- I understand that I will receive a copy of this signed and dated written ICF.
- I understand that photographs, images, and scans will be taken as described in this document and sent in a secure way to vendors working with Kalaris for review or reading.

I would like to use Scout Clinical's services as described in the "Will you receive any payment if you take part in the study?" section and agree to share the necessary personal information to provide these services.

☐ Yes, I agree to use Scout Clinical.

☐ No, I do not agree to use Scout Clinical.

_____

Printed Name of Subject, in full

_____

Signature of Subject Date (dd-Mmm-yyyy)

STATEMENT OF PERSON OBTAINING CONSENT

- I have presented the study and answered the subject's questions.
- I will give the subject a copy of this signed and dated ICF.

_____

Printed Name of Person Obtaining Consent (Study Doctor/Delegate), in full

_____

Signature of Person Obtaining Consent Date (dd-Mmm-yyyy)