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

Sponsor / Study Title:	**VIKING THERAPEUTICS, INC. / "VK2809 A PHASE 2B, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY, SAFETY, AND TOLERABILITY OF VK2809 ADMINISTERED FOR 52 WEEKS FOLLOWED BY A 4-WEEK OFF-DRUG PHASE IN SUBJECTS WITH BIOPSY PROVEN NON-ALCOHOLIC STEATOHEPATITIS WITH FIBROSIS"**
Protocol Number:	**VK2809-202**
Principal Investigator: (Study Doctor)	**Anuj Bhargava, M.D.**
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INTRODUCTION

You are being invited to voluntarily take part in a clinical research study to test VK2809 in subjects with non-alcoholic steatohepatitis (NASH).

This document tells you about the study and includes information about the reason why the study is being done, what will happen to you if you take part in the study, and the possible risks and benefits of this study. Please take time to read this document carefully and please feel free to talk about it with your partner, family members, family doctor or others.

Your study doctor will also talk to you about the information in this document in detail. Please ask your study doctor or the study staff to explain anything that is not clear.

If you choose to take part in this study, you will be asked to sign and date this document. You will get a fully signed and dated copy of this informed consent form.

Even if you choose to take part in the study and sign and date the consent form, you are still free to withdraw from the study at any time without giving a reason. If you withdraw from the study, we will ask you to return for an early termination final study assessment to check your health.

1. PURPOSE OF THIS STUDY

The purpose of this study is to find out about the safety and efficacy of *VK2809* for the treatment of *non-alcoholic steatohepatitis (NASH)*. VK2809 is an experimental drug which is not approved by Health Authorities including FDA for the treatment of NASH.

NASH causes the build-up of extra fat in the liver, resulting in a type of liver cell degeneration known as ballooning. No symptoms are usually detected with NASH; however, the formation of scars in the liver occur due to ballooning can cause serious damage over time. Ballooning and inflammation cause the emergence of NASH and are very likely driving the accumulation of scar tissue (called fibrogenesis) which is the main liver complication of NASH.

If liver damage progresses, its ability to function is impaired and cirrhosis can occur, significantly increasing the risk of bleeding, liver failure or liver cancer.

Up to now, the only available treatment for patients having NASH is to make lifestyle changes such as improving diet, exercising more and losing weight. These changes will allow the decrease of the level of fat in the blood and liver, and prevents NASH from getting worse. There are currently no medications approved on the market that can treat or reverse NASH.

This study will examine the safety and efficacy of an investigational thyroid hormone receptor drug, called VK2809, being developed to reduce cholesterol and lower liver fat content. The FDA has allowed the investigational use of VK2809 in this research study. This Informed Consent Form, or ICF, will also refer to VK2809 as the "study drug." Study treatment period refers to the period in the study when either study treatment or placebo will be taken.

About 337 subjects will take part in this study at a number of different locations in the United States of America, Mexico and Europe (France and Belgium). One of the institutions taking part in this study is listed on the first page of this document. The main study doctor for this institution is the doctor named as the Principal Investigator on the first page. Your study doctor will be helped by other study staff.

2. STUDY PROCEDURES

The study involves

- a screening period of up to 12 weeks
- a study treatment period of 52 weeks of scheduled visits to the clinic every 4 weeks
- then a follow-up period of 4 weeks

This study will have 16 scheduled study visits over a period of 64 weeks.

The total duration of your participation in the study will be approximately 64 weeks.

Because this is a study where you and your study doctor do not know which study drug you are getting, you cannot be told the exact study treatment option you get until after the study has ended and the results have been analyzed. Your study doctor can find out the study treatment if there is an emergency and it is needed for your health.

Subjects who qualify for this study will be assigned by chance to get one of the following study treatments:

- Study Treatment 1: VK2809 1.0 mg daily
- Study Treatment 2: VK2809 2.5 mg daily
- Study Treatment 3: VK2809 5.0 mg every other day
- Study Treatment 4: VK2809 10.0 mg every other day
- Study Treatment 5: placebo daily

You will have approximately 4 in 5 chance of being assigned to VK2809, and approximately 1 in 5 chance of getting placebo.

A 'placebo' looks like the study drug but does not have any active study drug in it. You and your study doctor will not know your treatment group. This is the best way to measure the effect of the study drug in the study and eliminate any potential bias towards the treatment you receive.

Before any study-related tests and procedures are performed, you will be asked to read and voluntarily sign and date this Informed Consent Form (ICF) as an indication that you agree to participate in the study. If you agree to take part in this study, you will first have some screening tests to find out if you meet the requirements. A Screening Period is a period in a clinical study to do tests to confirm your eligibility for the study before you can get the study treatment.

SCREENING VISIT

- You need to fast for a minimum of 8 hours for blood tests can be done.
- The study doctor will ask you questions about your demographics such as year of birth, gender, race/ethnicity, your medical history and about any treatments or medications that you may be taking, including non-prescription medication, vitamins or herbal remedies, your lifestyle habits including diet, physical activity, smoking status and alcohol intake.
- Your diet and exercise will need to be established for at least 3 months at the time of screening, and should not change during the study.
- A physical examination (PE) including measurement of your height, weight, vital signs (body temperature, respiration rate, heart rate and blood pressure) will be performed three times. You would need to refrain from consuming any caffeinated beverages for at least 30 minutes prior to blood pressure and pulse measurements.
- An MRI-PDFF to assess the percent of fat in your liver.
- You will begin 24-hour Holter monitoring. This small monitor is connected by small leads and measures the electrical activity of your heart.
- ECG: Leads will be placed on your chest, arms, and legs to measure the electrical activity of your heart. It takes about five minutes to place the leads and obtain the tracing. There will be three measurements taken with you laying down.
- Blood draw to test for pregnancy (for women who are capable of becoming pregnant).
- A liver biopsy might be done to obtain a sample of your liver if no previous sample is available within 6 months of screening.
- Blood draw for standard laboratory assessments such as the chemistry, hematology, liver, lipid, thyroid panels, and urinalysis to evaluate your well-being.
- Blood draw to test bone biomarkers (bone health), cardiac biomarkers (heart health), and NASH biomarkers (liver health).
- Alcohol and drug test

If you are found to be eligible to take part in the study, your study doctor will talk with you about what will happen during your study treatment visits.

At *every* study visit:

- You will need to fast for at least 8 hours (water allowed) prior to dosing.
- You will be asked questions about any symptoms, illnesses, medication changes and/or any visits to urgent care or hospital you have had since your last study visit. It is important to tell the study doctor or the nurse about any changes in health that may have happened even if you do not think that they are related to the study.
- You should tell your doctor or nurse of any changes in lifestyle habits since your last visit.

- You will be provided with the study treatment for the next 4 weeks. Bring back to the site at each study visit any remaining study treatment as well as its packaging (blisters and packaging, either used or not)

The "x" in the table below reflects the procedures that will only be done at *some* study visits:

- Genetic testing is optional and would be done at Visit 2 only.

Visit	Blood/ Urine Samples	PK*	PE**	Vital Signs	Alcohol/ Drug Test	Pregnancy Test	ECG	Holter Monitor	MRI-PDFF	Liver Biopsy	Dosing
V2	X	X	X	X	X	X	X	X			X
V3	X	X		X			X	X			X
V4	X	X		X							X
V5	X	X	X	X	X	X	X		X		X
V6	X	X		X			X				X
V7	X	X		X							X
V8	X	X		X							X
V9	X	X	X	X	X	X	X	X			X
V10	X	X		X							X
V11	X	X		X							X
V12	X	X		X		X	X				X
V13	X	X		X							X
V14	X	X		X							X
V15	X	X	X	X	X	X	X		X	X	X
V16	X		X	X	X	X	X				

*PK (pharmacokinetic) measures how your body metabolizes or handles the study drug
**PE (physical exam)

	Early Termination Visit: If you are withdrawn from the study, or choose to withdraw from the study, you will be asked to meet with your study doctor for a final visit to check on your health which will include:

Visit	Blood/ Urine Samples	PK	PE	Vital Signs	Alcohol/ Drug Test	Pregnancy Test	ECG	MRI-PDFF	Liver Biopsy
ET	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

•	• You will be asked to return all study drug (used and unused) • Assess lifestyle habits (physical activity, diet, alcohol intake) • MRI-PDFF to assess the percent of fat in your liver • Liver biopsy if you received at least 12 weeks of study treatment

STUDY PROCEDURE DESCRIPTIONS

- ✓ ***Blood and Urine Sampling***

Blood samples will be collected to check your health.

As previously described, your urine will be sampled throughout the study for various reasons, which may include:

- Routine safety tests: Routine urine analysis provides information about your overall health and includes sugar, salts, and indicators of healthy liver and kidney function.
- If you are a female of childbearing potential, a urine pregnancy test will be performed.

Your blood sample will be tested for HIV, which is the virus that causes AIDS. If your test results show that you have HIV, you will be told and given information on counseling services. The results of your HIV test will be kept confidential and disclosed only as required by law to local health authorities.

Blood samples will be tested for Hepatitis A, B, C and E. If your test results are positive, your study doctor or staff will tell you. The results of Hepatitis A, B, C and E testing will be kept confidential and disclosed only as required by law to local health authorities.

Biomarker research tests samples – Blood sample to test bone biomarkers (bone health), cardiac biomarkers (heart health), and NASH biomarkers (liver health).

Optional Genetic research tests samples – Blood will have genetic testing done to identify genetic variations potentially associated with increased risk of NASH and increased risk of formation of scar tissue. Genetic test samples will be stored for approximately 5 years.

Optional Pharmacokinetic (PK) Assessments – These assessments will measure how your body metabolizes or handles the study drug.

Your study site may be participating in the optional PK assessments and if so, you may be asked to participate if you are willing to do so. Therefore, there will be a subset of subjects who will be part of "Intensive PK" in which blood samples will be taken at the timepoints shown below. Intensive PK is not mandatory, and you will have the option to be a part of this PK assessment which would involve an overnight stay near the study site in order to collect blood at the 24-hour timepoint. The study site will arrange payment or reimbursement for the overnight stay and related expenses. Approximately 96 subjects in the study treatment and placebo group will contribute to these PK samples.

Visit 2, Day 1, Randomization	**Pre-dose:** within 30 minutes of study drug dosing **Post dose:** 1 hr (±15 minutes), 2 hrs (±15 minutes), 4 hrs (±15 minutes), 8 hrs (± 30 minutes) and 24 hrs ± 60 minutes)
Visit 15, Day 364 (Week 52)	**Pre-dose:** within 30 minutes of study drug dosing **Post dose:** 1 hr (±15 minutes), 2 hrs (±15 minutes), 4 hrs (±15 minutes), 8 hrs (± 30 minutes) and 24 hrs ± 60 minutes)

Early Termination Visit (as applicable)	**Pre-dose:** within 30 minutes of study drug dosing **Post dose:** 1 hr (±15 minutes), 2 hrs (±15 minutes), 4 hrs (±15 minutes), 8 hrs (± 30 minutes) and 24 hrs ± 60 minutes)

I agree or disagree to participate in the "Intensive PK" sampling as indicated by my answer below.

_____ Yes, I agree _____ No, I disagree

Human Biological Samples

While you are in this study, you will have sample(s) taken from you. These samples will be used for commercial medical research to support this study protocol which will be performed by the laboratory described below. These samples are valuable to this study and may help identify a cure for disease or identify a biomarker to help with treatment of disease.

- Your samples will be used for the research purposes explained in the procedures section of this form.
- Your samples will not be sold or used directly for the production of commercial products.
- The research done with your samples may help to develop new products, new medical tests or treatments in the future that have commercial value. The study sponsor, Viking Pharmaceuticals, will own the research results from your samples and may file patents or otherwise commercially exploit such research results. There will be no financial benefit to you for any activities or products that result from the use of your samples and data.
- Your samples may be provided to a third party for testing and research use and storage purposes done for and on behalf of the sponsor of this study and its third party collaborators. Samples being collected will be sent to:

  Samples being collected in North America will be sent to:

  COVANCE CENTRAL LABORATORY SERVICES L.P.
  8211 SciCor Drive
  Indianapolis, IN
  46214-2985 USA

  but may need to be shipped to other locations, which may be in other countries, during the course of the study.
- Your samples will be coded to protect your identity. Samples will be identified by your subject identification number.
- Your samples will be stored for five years. Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency.

Reports about research done with your samples will not be put in your health/medical record and will be kept confidential as described below in Section 9.

- ✓ ***ECG***

An electrocardiogram (ECG) will be performed after 10 minutes' rest while you are in a laying position. This is a test where sticky pads (electrodes) are attached to your chest and your heart activity and rate are measured. You may have minor discomfort from this procedure when the sticky pads are removed. It may feel like removing a band-aid. This test checks for problems with the electrical activity of your heart. It will be analyzed by your Study Doctor.

- ✓ ***24 Hour Holter Monitoring***

You will have Holter monitoring of your heart for 24 hours during the screening period, at visit 2 (randomization), visit 3 (week 4) and visit 9 (week 28). Prior to leaving the clinic, you will also be instructed in the process of removing the Holter monitor leads.

On an individual basis, arrangements will be made to return the Holter monitor equipment to the investigative site.

- ✓ ***MRI PDFF***

Magnetic Resonance Imaging- Proton Density Fat Fraction (MRI-PDFF) is a specialized type of MRI that measures the percent of fat in your liver. MRI scans use radio frequency waves (similar to those in an AM/FM radio) but no radiation and a powerful magnet to take pictures. You will be required to lie in a narrow cylinder.

- ✓ ***Liver Biopsy***

If a historical liver biopsy is available (performed within 6 months of the screening visit), the corresponding tissue slides will be sent to a centralized pathology laboratory in order to confirm that you can participate in this study.

If no historical liver biopsy is available, the study doctor will plan a liver biopsy during the screening period. As soon as this liver biopsy is done, the corresponding tissue slides will be sent to a centralized pathology laboratory to confirm the diagnosis of NASH. The samples will be identified using a code number so that your personal identity will be kept confidential.
A second biopsy will be performed at visit 15 (week 52).

The biopsy will be collected following the standard biopsy procedures and good medical standards of the hospital/clinic including a check of your blood clotting tests as needed before the procedure. You must arrive at the hospital/clinic in a fasting state. The local standard practice will be followed to help ensure that no complications are present when you leave the hospital/clinic. Liver biopsy will be performed under local or general anesthesia, according to the usual practice of the hospital/clinic. Your Study Doctor will provide you with all of the information regarding the liver biopsy procedure upon request.

If the liver biopsy fragment is too small or of bad quality, the central pathology lab may request other available slides or new slides be prepared from an available block of tissue.

Concomitant Medications:

The study doctor will discuss concomitant medications with you and decide if you can still qualify for the study.

3. YOUR RESPONSIBILITIES FOR THIS STUDY

If you decide to take part in this study, it is important that you agree to:

- Take/Handle the study drug following the instructions provided with the drug or by your study doctor or the study staff;
- Store the study drug in a safe place in your refrigerator, for your own use only and out of the reach of children; and return any unused study drug and all packaging at each study visit.
- Go to your study visits. As soon as you know that you will not be able to go to a study visit, please contact your study doctor or the study staff to schedule a new visit.
- Truthfully answer any questions from your study doctor or the study staff when asked about any changes in your health, lifestyle, visits to other doctors or hospital admissions, or changes in your medication, including prescribed medications, over the counter medications, herbal remedies, and vitamins. Review the list of prohibited medications during the course of the study through the last safety follow-up visit and inform the study doctor if you are taking any of these medications before or during the study.
- Inform your study doctor if you are or are planning to take part in other clinical research studies. Do not take part in any other clinical research studies without the consent of your study doctor while you are taking part in this study, to avoid any side effects between the study drugs/devices.
- Comply with contraception measures to prevent pregnancy. Tell the study doctor if you believe you or your partner may be pregnant.
- Tell your study doctor or research study staff if you change your mind about taking part in the study.
- Fast as instructed: It will be essential to fast overnight (at least 8 hours) prior to dosing and for 30 minutes after dosing, which means that you will not have eaten anything for at least 8 hours before each dose. You can drink water during the fasting period and should drink as much water as you need while you are fasting.
- Refrain from exercise and heavy physical activity for at least 24 hours prior to each clinic visit
- Not excessively drink alcohol throughout the study. Your Study Doctor will inform you what is considered to be excessive alcohol drinking for you.
- Agree to maintain diet and exercise regime from the start of the study until study completion.

4. POSSIBLE RISKS

We ask you to think carefully about the possible risks or discomforts involved in the study before you agree to take part in this study.

If, by chance, you get a placebo for the study, you will not be receiving anything for your health problem, so it may stay the same, improve or get worse.

As the study drug is experimental, even if you get active drug, it may not help your health problem(s), which may stay the same, improve or might get worse.

Side effects of the study drug

There may be side effects of the study drug.

To date, there have been five phase 1 studies and one phase two study completed and approximately 200 subjects have received VK2809 in those clinical studies. The overall frequency of adverse events has been similar in subjects receiving VK2809 and subjects who received placebo. The following adverse events (side effects) were reported with the use of VK2809:

- Abdominal (belly) discomfort
- Abdominal distension (bloating)
- Abdominal pain
- Increased liver function test (ALT, AST, bilirubin)
- Anxiety
- Arthralgia (joint pain)
- Asthenia (feeling weak and having no energy)
- Chest discomfort, Chest pain
- Cough
- Diarrhea
- Dizziness
- Eosinophilia (increase in cells that fight infections)
- Fatigue (feeling tired)
- Feeling hot
- Headache
- Hunger
- Insomnia (difficulty falling asleep or staying asleep)
- Irritability
- Nausea
- Palpitations (fast, hard heartbeat)
- Paresthesia (abnormal sensation, such as pins and needles)
- Pruritus (itchy skin)
- Restlessness
- Urinary incontinence (loss of bladder control)
- Urine color abnormal
- Ventricular extrasystoles (irregular heartbeat)
- Ventricular tachycardia (fast heartbeat)

Increases in liver function test levels (alanine transaminase or ALT and aspartate transaminase or AST) have been reported in subjects who received VK2809 and have also been reported in subjects who received the placebo. The increased ALT and/or AST returned patients' to normal levels either with continued study drug treatment or after the study treatment period ended. Most of these elevations were considered mild elevations; none represented damage to the liver. You will be monitored with blood tests to look for any increase in your liver function test levels.

You should always tell your study doctor about new, increased or unusual symptoms you are experiencing, including any symptoms similar to those listed below.

Potential risks include:

- Increase in thyroid hormone activity which may cause signs and symptoms including sweating, increase in the heart rate or number of times your heart beats every minute, irregular heart rate, feeling like your heart is racing or a fluttering in your chest, increase in blood pressure, chest or heart pain, heart attack, heart failure with chest pain, fluid in the lungs, shortness of breath, anxiety or nervousness, tremors, feeling weak in your muscles, an increase in bowel movements or diarrhea, decrease in appetite or weight loss, or any problems completing your normal daily activities.
- Decrease in thyroid hormone activity which may cause symptoms that include fatigue, weakness, cold intolerance, weight gain, constipation, difficulty with your thinking processes, hoarseness, dry skin, swelling, pain in the joints and muscles, and decreased hearing. Signs of a decrease in thyroid function may include a slow heart rate, coarse skin, swelling around the eyes, enlargement of the tongue, and diastolic hypertension (a type of high blood pressure).
- There are also other medical conditions that can cause the symptoms described above. If you have any of the symptoms described above, please let the study doctor know. You will be monitored with blood tests to look for any increase or decrease in the thyroid hormone in your blood.
- Changes in your heart rate and/or heart rhythm could occur. Based on limited experience with this study drug, clear effects on the heart have not been seen in human studies. In animal studies using rats and monkeys, rats treated with the study drug have shown some cellular death in the heart and increased heart weight in some studies at drug blood levels that are expected to occur in people in this clinical study. Not all the effects of the study drug on heart in rats were reversed after the drug was stopped. Increases in heart rate occurred at drug blood levels that were much higher than those expected to occur in this clinical study. Your heart will be monitored throughout the study to see if there are any changes in your heart rate and/or rhythm. Blood levels of certain heart tests will also be collected throughout the study to monitor your heart.

Heart Monitoring

In order to assess whether you are experiencing changes in heart rate or heart function, you will be questioned and examined with electrocardiograms, Holter monitors and will have your pulse and blood pressure measured as outlined earlier in this consent document. If certain changes in your heart are found, you may need to stop taking the study drug and/or be closely monitored by other health care professionals (a cardiologist, for example).

Interactions with Other Medication Risks

It is also possible for VK2809 to interact with and change the blood levels of other drugs. As a precaution, you will not be permitted to take these drugs while in this study. Conversely, some drugs can change the blood levels of VK2809 if given at the same time. Your study doctor has a complete list of drugs that you should not take while on this study. It is therefore extremely important to not take any medication or over-the-counter drugs before discussing it with your study doctor. An example of an over-the-counter drug is Tylenol®; these are drugs that you can buy without a prescription.

If you require treatment outside of the research study, please make sure to tell the clinic or doctor that you are participating in this research study.

Unknown Risks

It is important to know that there may be other side effects that are not yet known.

It is important to tell the study doctor or study nurse right away about any changes in health that may have happened even if you do not think they are related to the study or to the study drug.

Your study doctor may give you treatment to help control side effects.

Pregnancy risks

Female subjects

The effects of the study drug on an unborn child and on a breast-fed baby are not known. Because of this, it is very important that you are not pregnant and are not breast-feeding and you do not become pregnant during the course of the study. You will not be allowed to take part in the study if you are pregnant, trying to become pregnant or are breast-feeding.

- If you can become pregnant, the study doctor will ask you to have a blood pregnancy test before you start the study, and urine pregnancy tests during the study to make sure that you are not pregnant.
- If you can become pregnant, you must use a reliable birth control method(s) during the study and for 28 days after the last dose of study drug. The study doctor will let you know which birth control methods are acceptable. If you do become pregnant while taking part in the study you should let your study doctor know right away. Your study doctor will stop the study drug and talk to you about the need for further medical attention. Your study doctor will continue to follow your pregnancy and the health of your newborn for about 8 weeks after birth.

Male subjects

The effects of the study drug on an unborn child are not known and there may be risks with taking part in this study if your partner gets pregnant.

- You and your partner must use a reliable birth control method during the study and for 28 days after the last dose of study drug. The study doctor will let you know which birth control methods are acceptable.
- If your partner does become pregnant while you are taking part in the study you should let your study doctor know right away. Your study doctor may *ask your partner to sign a Pregnant Partner Data Release Form* to gather information about the pregnancy and health of the newborn for about 8 weeks after birth.

Other Possible Risks or Discomfort

There are also possible risks and discomforts from the procedures you may experience during the study. These include:

- Blood drawing may cause some pain and carries a small risk of bleeding, bruising, or infection at the puncture site. There is discomfort when a needle is inserted to withdraw blood from a vein. Occasionally, a small accumulation of blood (hematoma) or infection may occur at the point of insertion. There is also a risk of feeling dizzy or fainting. During the study, about 475 mL (97 teaspoons) will be taken from you.

- Liver biopsy: Biopsies can cause pain, redness, swelling, excessive bleeding, bruising, or draining at the needle site. Abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site can also occur. Your study doctor will explain the details and risks of the procedure, which may vary depending on how the biopsy will be obtained.
- MRI PDFF: There may be some discomfort from claustrophobia (fear of being trapped in a closed space), if you think you will feel claustrophobic, please tell the study doctor. The sounds of the MRI machine itself could be uncomfortable. The MRI can be stopped at any time at your request. Please inform the study doctor if you have metal in your body, since you may not be able to have an MRI scan. Also, if you have a pacemaker you should not have an MRI scan. There are no risks or side effects from the magnetic fields of the MRI. You should notify the doctor if you feel any of these symptoms.
- The ECG and Holter Monitoring leads (small stickers with adhesive on them that are attached to your body) infrequently may cause redness, itching, or mild pain on your skin.

5. POSSIBLE BENEFITS

Possible benefits from taking part in this study may include:

- Your health problem may or may not get better from taking part in this study, it is hoped that the study drug may provide relief of, or lessening of, the sign and symptoms of your health problem, however such benefit cannot be guaranteed. In this study you may get a placebo which means you may not be taking the actual study drug during the study.
- Taking part in this study will help doctors to learn more about the study drug. This may help others with your health problem in the future.

We cannot promise that you will get any benefits from this study.

There is no recovery time from taking VK2809. Ask the study doctor for your estimated recovery time from the procedures done during your participation in this study.

6. ALTERNATIVE TREATMENTS

If you decide not to take part in this study or study treatment is stopped, you may want to think about other treatments for your health problem and your study doctor can talk with you about these other treatments and their risks and benefits.

7. COSTS AND REIMBURSEMENT FOR PARTICIPATION

The study treatment, office visits, medical tests and procedures that are part of the research study and are not standard of care will be provided at no cost to you or your insurance company. The study sponsor, Viking Therapeutics, is paying Covance for the work performed by the study doctor and study staff in this study.

You or your insurance company will have to pay for procedures or tests that are part of the standard treatment for patients with your health problem.

You will be paid for your inconvenience, a $40 travel stipend every time you come to the office for a study visit. In addition, you will receive $250 twice during the study for your Liver Biopsies, $25 four times during the study for wearing a Holter Heart Monitor, $25 four times during the study for your MRIs, as well as $0.58 per mile stipend for traveling to get your MRIs. You will be paid following each completed visit. For more information, please talk to your study doctor.

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

8. COMPENSATION FOR INJURY

If you become physically ill or are injured while you are participating in the study, get the medical care that you need right away and contact the study doctor at the number listed on the first page of this form as soon as possible.

A research related injury or illness is a physical injury or illness that is determined by the study doctor and the study sponsor to be a direct result of your receiving the study treatment or undergoing a study-related procedure (one that is not performed as part of your regular care and would not be performed if you were not participating in this study) in accordance with the study Protocol.

A research related injury or illness does not include worsening or advancement of the illness for which the study treatment was given, medical conditions associated with the worsening or advancement or such illness, or any medical condition you may have had before receiving study treatment except to the extent it is made worse by the study treatment or study specific procedure. If you sustain a research injury or illness, first aid will be given immediately.

All reasonable medical expenses NOT covered by your personal medical insurance will be paid by the study sponsor or the participating research site if the expenses are due to a research-related injury or illness and you have followed the study requirements and immediately notified the study doctor of the injury. The sponsor carries insurance to cover research-related physical injuries or illnesses. There is no plan for any additional financial compensation (money) from the sponsor. Financial compensation for such things as lost wages, disability or discomfort due to the injury is not offered by the sponsor.

If the injury or illness is the fault of the study site, the study doctor, study staff, or third parties, or resulted from something that was done that was not in accordance with the study Protocol, or resulted from your own actions or inactions, such as your failure to follow your responsibilities under this informed consent form or the directions of your study doctor, the sponsor will not cover the cost of care for your injury or illness. You do not give up any of your legal rights related to compensation and treatment for research-related injuries or illness by signing this form. Should you require further information about compensation and treatment for research-related injury or illness, you should talk with the study doctor.

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

9. CONFIDENTIALITY

Your identity and your personal health data will be kept confidential.

Without your consent, your data or samples cannot be used. This is why you will not be able to take part in the study if you do not give your consent to use your personal data.

During the course of the study, the study doctor will collect your personal data (including personal health data about you) and biological samples, which will be used for the purpose of the study as described in section 1 of this Informed Consent Form and may help develop new tests, procedures, and commercial products.

You must give your authorization before the study doctor can use or share your personal data with others. This section will describe how your personal data will be collected and used and explain your rights.

By signing and dating this form, you consent to the study doctor and his or her study staff collecting and using personal data about you and your biological samples for the study ("Study Data") as permitted by the applicable laws and regulations.

Your consent to the use of Study Data for the purposes of the Study does not have a specific expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document. You may withdraw your consent at any time by writing to the study doctor at the address listed on page one of this form. If you do take away your consent, no new information or biological samples will be taken and you may also request that no new analysis on your samples will be done. If you withdraw your authorization, you will not be able to continue in the study.

Data Collected

The Study Data that will be collected are:

- Personal data
    - your name, address, telephone number, email address, health insurance number, national identification number (at your doctor's office only)
    - your age, gender, ethnic and racial background
    - information about your lifestyle, health, medical condition and medical history and medications you take
- Biological Samples (see section 2 above): blood [approximately 475 mL (97 teaspoons)
    - For the Sparse PK samples blood: approximately 75 mL (14 teaspoons) which is included in the approximate blood amount listed above
    - For Intensive PK samples blood: An additional approximately 50 mL (10 teaspoons) would be added to the 475 mL blood amount collected
- Information about your study treatments and response to study treatments (which includes the procedures described in this form) and data resulting from analysis of biological samples and images
- Information about side effects and medical history and tests while you are taking part in the study

Data Protection

Your full identity will not be on any of the study documents or samples taken and kept by the sponsor for their studies. The study site will remove personal data, including personal health data, relating to you from Study Data before these are transferred or otherwise made available to the study sponsor.

The Study Data given to and used by the sponsor is protected by the use of a subject identification number, which is a number specific to you. Only a unique subject identification number for the study will link the data or samples to you. These data may contain your gender and race, as well as any medical and scientific data required by the study. The study doctor maintains a confidential list that links the subject identification number to you. Only the study doctor will be able to connect the subject identification number to your personal data. He/she will not share this information except as explained in this consent form. The site will also

establish the necessary technical and organizational measures to prevent your re-identification by the study sponsor.

The sponsor, the sponsor's representatives, regulatory authorities, or other supervisory bodies may review any encoded Study Data held by the study doctor and the site. The reason these people may look at your encoded Study Data is to make sure the study has been done the right way and that the Study Data are accurate and for regulatory purposes. The only circumstances in which the sponsor, the sponsor's representatives, regulatory authorities, data safety monitoring board, or other supervisory bodies may review un-encoded Study Data (Study Data that identifies you) would be where this is necessary to comply with the national law of the United States or is necessary for the performance of a task carried out in the public interest. In particular, the only circumstances in which sponsor's representatives may review un-encoded Study Data would be where the national law of the United States requires this review such as for verification of clinical study procedures and/or data, and as part of an investigation of an adverse event that occurred during the study, without violating your confidentiality. Encoded and un-encoded Study Data may be reviewed on-study site at the study facility or remotely by way of electronic records that the study facility would provide access to or through a website/portal (both provide confidential and secure limited access). A data safety monitoring board is established to oversee the study and can access un-encoded data. These people and organizations are all obligated to maintain confidentiality by the nature of their work, or are bound by confidentiality agreements.

The sponsor may share the encoded Study Data with its representatives, including authorized study monitors, with other companies within its group, with its service providers, its contractors and business collaborators, and with research institutions and research-based commercial organizations who will use the encoded Study Data for the purposes described above.

The sponsor and those who work for or with the sponsor, the IRB, and national and international Regulatory Authorities, including the U.S. Food and Drug Administration (FDA), will be able to see your personal medical files at the study site, which contain your full name. All people involved in the study have the duty of confidentiality.

Despite these steps taken to limit access to your personal data, including the use of the subject identification number as described above, people may develop ways in the future that would allow someone to link your health information in study databases back to you. For example, someone could compare information in the

databases with information from you in another database and be able to identify you. It also is possible that there could be security breaches of the computer systems used to store the codes linking your medical information to you. There may also be other privacy risks that are not yet foreseen. All reasonable steps will be undertaken to ensure the confidentiality of the Study Data.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Publication

On completion of the study, results and data from the study that will not include any personal identifiers may be published in accordance with regulatory requirements.

Although information about this study, including the results, may be published for scientific purposes, presented or posted electronically (for example, in a clinical trials registry database) or presented to scientific groups, your name and personal information will not be used and your identity will not otherwise be revealed.

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.

Storage of Personal Data and Biological Samples

Your personal data will be stored for as long as required by law which will be until at least 2 years after VK2809's last approval and the sponsor does not intend to apply for any further approval or at least 2 years have gone by since the sponsor decided to no longer study VK2809, whichever is longer. Information on how long your biological samples will be stored is provided in the biological samples section.

Rights Concerning the Processing of Your Personal Data

The data recorded at the time of this study may be held on computer or as paper records by the sponsor or by someone else for the sponsor. You have a right of access to, and, if needed, you have the right to correct your data. You have the right to request from sponsor erasure of your personal data, to obtain from the sponsor restriction of processing, to object to processing, and to receive personal data provided to sponsor for transfer to a third party (i.e., right to data portability).

However, certain personal data collected before you make such a request may need to be processed by the sponsor in order to comply with applicable regulations governing clinical research and cannot, therefore, be erased. You also have the right to withdraw your authorization at any time by writing to the study doctor listed on page one of this form.. However, if you withdraw your authorization to the processing of your personal data after you have started your participation in the study this will result in your withdrawal from the study.

If you have any questions about the collection and use of information about you, or would like to exercise rights that you may have regarding this information, you should ask your study doctor at the phone number listed on page one of this form.

If you decide not to sign and date this form, you will not be able to take part in the study.

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 and dating this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Authorization Date

10. NEW INFORMATION

During the study, new information about the risks and benefits of the study drug or procedures may become known. Your study doctor will talk with you about any important new information that is learned during the course of the study that may affect your willingness to continue to take part in the study. This new information may also mean that you can no longer take part in this study. In all cases, you will be offered all available care to suit your needs and/or medical condition.

11. VOLUNTARY PARTICIPATION/WITHDRAWAL

Taking part in this study is entirely voluntary. You do not have to take part in this study.

If you choose to take part and you change your mind later, you are free to take back your consent and to stop being in the study at any time without giving a reason. In that case, we ask you to tell your study doctor or study staff. You may be asked to take part in a final visit or follow-up. If you leave the study early, then you will be asked to return for a final visit which includes the procedures detailed in section 2.

If you do take away your consent, no new information or biological samples will be taken and you may also request that no new analysis on your samples will be done.

If you change your mind about allowing your coded samples to be used for this study, contact the study doctor or nurse and let them know. Your **samples** will no longer be made available for testing and will be destroyed. If you do choose not to have your samples that are required for the study to be used, you will no longer be able to take part in this study but you will not lose any benefits to which you are otherwise entitled.

If you want to stop being in the study, please let your study doctor know. The study doctor will discuss with you any options which may allow for the collection of further follow-up information on your health until the end of the study. This may be by coming to the regular study visits, or you may get regular telephone calls from the study site, or you may also allow a relative or primary doctor/General Practitioner/family doctor to provide the necessary information. The collection of this information is important to assess the results of this study. If you choose to refuse to provide any further information for the study, you should explicitly inform your study doctor about your decision and this should preferably be done in writing. If you withdraw from the study, your vital status may be obtained at study end through review of your medical records or via public information according to local guidelines and as allowed by local regulations unless you object and notify your study doctor.

Your choice to take part or to stop taking part in this study, will not affect your routine/regular treatment, your relationship with those treating you or your relationship with the place where you are getting treatment. You will still receive care for your condition and will not lose any benefits to which you are otherwise entitled.

12. PREMATURE END OF THE STUDY OR STUDY TREATMENT

This study or the study treatment may be stopped without your consent.

Reasons why the sponsor can stop the study or put the study on hold include:

- The study drug has been shown not to work.
- The study drug has been shown to work and there is no need for the study to continue.

- Decisions made in the business or commercial interests of the sponsor.
- Decisions made by the FDA or IRB.

Reasons why the study doctor can stop your study treatment include:

- Taking part in the study is not beneficial to you.
- You are having bad side effects.
- You are not coming to study visits or taking medications, as told.
- You need to get other treatments for your medical condition that the study does not allow.

13. WHOM TO CONTACTABOUT THE STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator 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, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00039259.

OPTIONAL GENETIC TESTING

You may volunteer to participate in optional exploratory research. The testing will be done to analyze genetic factors and substances that may provide information about how the drug works, the causes of disease and its individual course, identification of subjects who may benefit from the study drug, or who are at risk for certain side effects. This information could improve the treatment of subjects in the future.

Exploratory research can help to improve our understanding of how individuals respond to drugs and our ability to predict, detect, and monitor diseases and their progression. If you agree to participate, your samples may be used to study genetic material (instructions for cells to work that is in the form of DNA and RNA), proteins or parts of proteins (a part of all cells), and/or other molecules of cell metabolism (sugars), and fats.

The reason for genetic testing in the study is the following:

- To explore and identify potential changes biomarkers that may inform the scientists understanding of both your and future diseases and/or therapeutic treatments
- To search for and understand information to develop safer, more effective drugs/vaccines
- To ensure that subjects receive the correct dose of the correct drug at the correct time.

- To better understand why some people are more likely to respond to medicines than others
- To better understand why and how diseases can affect people in different ways
- To develop new treatments for diseases or medical conditions
- To discover the reasons why some people can be more likely to have side effects to medicines than others
- To understand what happens to medicines in people's bodies and how it affects them
- To develop better ways to treat diseases
- To develop or improve tests for diseases
- To do genetic tests to try to answer broad health research questions across disease areas

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

What will be done:

If you agree to participate, a blood sample will be collected. Please refer to the "Other Possible Risks or Discomfort" section to review risks associated with blood draws.

The optional genetic test sample will be collected at visit 2 and approximately 4 mL (1 teaspoon) will be collected for this testing.

Will I be provided with the results of these analyses?

No. You will not be provided the results of this further biomedical research genetic testing as this is exploratory research and is not designed to provide any information that is useful to you or your doctor. Exploratory research tests are performed under conditions which are different from the types of laboratory testing that your doctor may do. Therefore, it would not be appropriate to provide you or your doctor these results. Research information from this further research will not become part of your medical records

Storage (location and time period):

Samples for genetic polymorphisms will be stored until 5 years after study closure.

If you have agreed for your blood to be used for future research, then they will be stored for 2 years after study closure in a secure biorepository, at which point they will be destroyed per the central laboratory destruction process.

Your samples will not be sold to other people or companies.

Coding and Confidentiality Considerations:

Your samples will be coded to protect your identity.

Your samples will be labeled with the identification number used for you in the study. They will not be labeled with personally identifying information such as your name. The samples and your health information will have the same level of protection as samples used in the main study.

Your samples will initially be shipped to:

COVANCE CENTRAL LABORATORY SERVICES L.P.
8211 SciCor Drive
Indianapolis, IN
46214-2985 USA

but may need to be shipped to other locations, which may be in other countries. The Sponsor has the right to destroy your samples for any reason.

Access to your coded samples and data will only be given to those granted access by *Viking Therapeutics, Inc.*

Property Rights:

You will not receive any benefit from providing your samples for this optional research. The research performed on these samples may benefit other patients in the future.

FREEDOM TO REFUSE OR WITHDRAW YOUR SAMPLES FOR OPTIONAL RESEARCH

You can change your mind at any time about allowing your coded samples to be used for optional research. If you do change your mind, contact the study doctor or study nurse and let them know. Then your samples will no longer be made available for the optional research explained in this consent and will be destroyed. Whether or not you allow us to use your coded samples in this optional research, your choice will not have any effect on taking part in this study or taking part in future studies.

Data already obtained at the time of consent withdrawal from previous testing on samples will continue to be kept only in an anonymized form.

If you decide to leave the study, we will continue to use your samples already obtained as explained in this consent form unless you request that they be destroyed.

STATEMENT OF CONSENT

Sign and date this form ONLY if all of the following statements are true:

- I have read the information in this document in a language that I understand well.
- The content and meaning of this information have been explained to me.
- I have been given an opportunity to ask my questions in private as well as to meet with a study doctor to discuss this study. I have had a chance to consider the information, including the risks and benefits of taking part in this study, to ask questions, and to discuss the study. My questions have been answered to my satisfaction.
- I have asked the staff any questions I may have and have had enough time to decide if I want to take part in this study.
- I consent to my personal data, including personal health data, being collected, processed and stored as described in this consent form, in accordance with the procedure defined in this consent form.
- I agree that biological samples may be collected from me as explicitly stated in this consent form and I consent to such samples being analyzed and stored as described in this consent form.
- By agreeing to take part in this clinical research study I agree to give up my rights in any commercial value resulting from my samples and data. I agree that the study sponsor, Viking Pharmaceuticals, will own the research results from my samples and data, and there will be no financial benefit to me for any commercial findings or products that result from my samples and data. I also agree to the HIV testing as described in this document.
- **I have decided to take part as a subject in this clinical research study. I understand I will get a signed and dated copy of this document.**

I give permission for the use of my coded samples for the optional genetic testing study described above. *(Please initial one)*
____ Yes _____ No

I agree that my primary doctor can be told that I am taking part in this clinical research study (initial on the appropriate line).

____ Yes _____ No ____ Not applicable, I do NOT have a primary doctor

I am free to stop taking part in this study at any time for any reason and my choice to stop taking part will not affect my future medical care. I agree to follow the study doctor's instructions and will tell the study doctor at once if I have any changes in my health. By signing and dating this document, I am not giving up any of my legal rights.

Printed Name of Subject

Signature of Subject *Date of Signature*

Signature of Authorized Representative (if applicable) *Date of Signature*

I, the undersigned, investigator / study personnel, confirm that I have verbally given the necessary information about the study, that I answered any additional questions, and that I did not exert any pressure on the subject to participate in the study.

I declare that I acted in full accordance with the ethical principles described in GCP Guidelines, and other national and international legislation in effect.

A copy of this consent form, signed and dated by both parties, will be provided to the subject.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent *Date of Signature*