CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Title: **A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of VK2809 Administered for 12 Weeks Followed by a 4-Week Off-Drug Phase in Patients with Primary Hypercholesterolemia and Non-Alcoholic Fatty Liver Disease**

Sponsor: **Viking Therapeutics, Inc.**

Protocol Number: **VK2809-201**

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Please read all the pages of this informed consent form (ICF) carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether or not to take part in this research study. You are also encouraged to review this form with your family and with your regular healthcare provider. If you decide to take part in this research study, you must initial each page of this ICF, and then sign your name at the end of the ICF and date it. Nothing else can be done as part of this research study until you sign this ICF.

In this document, you will see the terms "treatment" and "treatment period"; these are terms used in research studies and are not meant to indicate that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug (VK2809) and parts of the study where you will be receiving this investigational product.

PURPOSE OF THE RESEARCH STUDY

Hyperlipidemia is a disease in which cholesterol or triglycerides and associated lipoproteins are elevated in the bloodstream.

Hyperlipidemia contributes to the development of cardiovascular disease and fatty liver disease. In recent decades, lipid-modulating drugs have emerged as a very successful way to treat hyperlipidemia and reduce the risk of cardiovascular disease. More recently, drugs that target the thyroid hormone receptor have also been investigated as a new way to help regulate low density lipoproteins.

This study will examine the safety and effectiveness of an investigational thyroid hormone receptor drug, called VK2809, which may help reduce cholesterol and lower liver fat content. This study is experimental. An "investigational drug" means that VK2809 is being tested and has not been approved by the Food and Drug Administration (FDA) for use by the general public. The FDA has allowed the investigational use of VK2809 in this research study. This ICF will also refer to VK2809 as the "study treatment."

This study is divided into four arms:

1) Placebo (A placebo is a capsule that looks like the VK2809 but does not contain active drug),
2) 5 mg of VK2809 taken once daily,
3) 10 mg of VK2809 taken once daily, or
4) 10 mg of VK2809 taken once every other day,

If you qualify for participation, you will be randomized to one of these four arms randomly (like flipping a coin). Neither you nor the study doctor will know which treatment you receive. You will take the assigned treatment for 12 weeks and then you will be monitored for an additional 4 weeks so that the study doctor can verify safety and determine how long the drug continues to work after you stop taking it.

Taking part in this research study is entirely **voluntary**. It is important for you to be completely honest and truthful with the study doctor regarding your health history and medical condition so that you do not pose an increased risk to your health by participating in this study.

Viking Therapeutics, Inc. is the Sponsor of this research study and is paying for the research study. In this ICF, Viking Therapeutics, Inc. is also called the "Sponsor."

INFORMATION ABOUT THE STUDY:

This study will enroll approximately 80 subjects in total (20 subjects per study arm) and will take place at multiple locations in the United States. The study will last for approximately 18-24 weeks, although you may complete the study sooner depending on your individual time in between research center visits and whether or not you are currently on lipid-lowering medication. You will be required to visit the research center once for **Screening**. If washout of medication is required or you do not arrive at Screening in a fasted state, you will visit the research center again for blood tests and for safety monitoring before receiving any treatment. You will be required to visit the research center 9 times (10 times if you have a wash-out period) during the 12-week **Treatment Period** to receive VK2809 and have tests performed, plus receiving a telephone call to review side effects. Finally, you will be required to visit the research center once for a **Follow-Up** safety visit.

- **Screening:** The results of this screening visit will help the study doctor decide if you meet certain medical requirements for taking part in this study. If you do not arrive at Screening in a fasted state, you will be required to return in a fasted state for important blood tests.

  You may also be asked to return for an additional visit during screening to have another set of safety blood tests performed if needed to establish a second baseline value. If you currently take lipid lowering medication, you will be required to stop this medication in order to participate in this research.

  A washout period of 6 weeks (and no more than 8 weeks) will be required before you can receive the study treatment. Therefore, you will be off your medication for about 20 weeks and may restart your medication once treatment phase is completed. Discuss this with your study doctor or personal doctor before deciding whether to participate in this study.

- **Treatment Period:** You will receive your first dose of study treatment (or placebo) at the research center. Over the following 12 weeks, you will have 6 more visits to the research center where you will have tests performed and the study doctor will make sure you are taking the study treatment as directed.

  You will be required to arrive for your visits in a fasted state for important blood tests. You will also visit the clinic twice very briefly to return equipment that was provided to you. Finally, you will receive one telephone call around Week 10 to review side effects.

- **Follow-Up:** You will return to the research center at approximately 4 weeks after the end of the Treatment Period. During this visit, you will be required to arrive fasted for important blood tests. The study doctor will be looking at information about your health since the time you received the study treatment. This information will be used to help determine if the study treatment has any lingering side effects or safety concerns.

More about these three different parts of the study can be found below.

For your safety, you should tell your regular health care provider that you are in this study. From your screening visit to the end of the study, you should inform your study doctor of any changes in your medications.

WHAT WILL HAPPEN DURING THE STUDY?
PART ONE- SCREENING:
Visit 1 (Screening):
At this visit, your study doctor will do the following:

- You will be asked to sign the informed consent form after discussing the form with the study doctor and study staff.
- You will be evaluated to determine if you are eligible to take part in the study.

- You will be asked about your demographics (for example: date of birth, race/ethnicity, sex and smoking status).
- You will be asked to review your past medical conditions and the medications or vitamins you are currently taking (prescribed or over the counter).
- You will be asked about your lifestyle habits, including alcohol intake.
- You will have a routine physical examination, including height, weight, and waist circumference.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism/thyrotoxicosis (higher than normal thyroid function).
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will give approximately 7 teaspoons of blood for various tests, including the following:
    - Routine safety tests
    - Pregnancy Test (for women who are surgically sterile but not naturally postmenopausal); Follicle Stimulating Hormone (FSH, for women who are post-menopausal)
    - Infectious Disease Testing (Hepatitis B, Hepatitis C, and HIV). You will be told if the test results are positive. A positive result from these tests will be reported to the local health department as required by state law. The results from these tests are confidential and results will not be shared outside of this study except as required by state law. There is always a chance that a breach in confidentiality could happen; this means that people that were not originally supposed to have this information could see these results. Please speak to the study staff or your personal doctor, if you want to know more about what it could mean to you if somebody outside of this research study has access to this information.
- You will provide urine for routine safety tests, alcohol testing, and drug testing.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart. 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.
- You will begin 24-hour Holter monitoring after all procedures have been completed. This small monitor is connected by small leads and measures the electrical activity of your heart. You will visit the clinic the following day to return the monitor. You will also be provided with a Holter diary to record comments.

*If you have not arrived having fasted for a minimum of 10 hours, you will be asked to return in a fasted state. As soon as the doctor receives the results of your blood tests and confirms that you continue to meet all criteria, you will be asked to stop any lipid lowering medications that you currently take.

You may be asked to return for an additional visit during screening to have another set of safety blood tests performed if needed to establish a second baseline value.

Once it has been confirmed that you meet all criteria for the study during screening, you will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver. This will be scheduled to occur approximately 1-2 weeks prior to Visit 3.

Visit 1a (24 hours after Visit 1):

- You will visit the clinic only to return the Holter monitor and the Holter diary card.

Visit 2 (For Washout Only, 6 weeks before receiving the Study Drug):

If you were asked to discontinue use of your lipid-lowering medications, you will be asked to return for Visit 2. At this visit, your study doctor will do the following:

- You will be asked to review your past medical conditions and the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down. Your weight and waist circumference will be measured.
- You will be asked to discontinue use of all lipid-lowering medications for the entire course of the study.

PART TWO – TREATMENT PERIOD :

Visit 3 :

If you are eligible for the study, you will need to return to the study center following a minimum 10-hour fast. The following will take place when you check into the research center:

- You will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver. This will be scheduled to occur approximately 1-2 weeks prior to Visit 3.
- You will be evaluated to once again verify that you are eligible to take part in the study.
- You will be asked to review your past medical conditions and the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- You will have a routine physical examination, including weight, and waist circumference.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism/thyrotoxicosis.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will give approximately 7 teaspoons of blood for various tests, including routine safety tests.
- You will provide urine for routine safety tests.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your first dose of study treatment. 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.
- You will begin 24-hour Holter monitoring 2 hours before receiving your first dose of study treatment.

This small monitor is connected by small leads and measures the electrical activity of your heart. You will visit the clinic the following day to return the monitor. You will also be provided with a Holter diary to record comments.

- The study doctor will administer your first dose of study treatment (which may be placebo).
- You will be dispensed study treatment, provided with instructions on how to take the study treatment, and instructed to ensure that you return any unused study treatment at each visit.

Visit 3a (24 hours after Visit 3):

- You will visit the clinic to return the Holter monitor and the Holter diary card and to give blood for various tests.

Visit 4 (approximately 1 week after Visit 3):

You will **not** take your daily morning dose of study treatment on the morning of Visit 4. Instead, you will report to the research center following a 10-hour fast. The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down. Your weight and waist circumference will be measured.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- The study doctor will review how well you complied with dosing instructions.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your dose of study treatment. 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.
- You will give approximately 2.5 teaspoons of blood for various tests, including routine safety tests. You will provide approximately 1 teaspoon of blood for pharmacokinetic (PK) analysis prior to receiving your daily dose of study treatment and again approximately 4 hours after receiving your daily dose. PK is what the body does to a drug as it moves into, though, and out of the body.
- The study doctor will administer your dose of study treatment (which may be placebo).
- You will be asked about any side effects you are experiencing or have experienced since your last visit.
- You will begin 24-hour Holter monitoring 2 hours before receiving your dose of study treatment. This small monitor is connected by small leads and measures the electrical activity of your heart. You will visit the clinic the following day to return the monitor. You will also be provided with a Holter diary to record comments.

Visit 4a (24 hours after Visit 4):

- You will visit the clinic only to return the Holter monitor and the Holter diary card.

Visit 5 (approximately 4 weeks after Visit 3):

You will **not** take your daily morning dose of study treatment on the morning of Visit 5. Instead, you will report to the research center early in the morning following a 10-hour fast. The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- The study doctor will review how well you complied with dosing instructions.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down. Your weight and waist circumference will be measured.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart prior to dosing. 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.
- You will give approximately 6.5 teaspoons of blood for routine safety tests.
- You will provide urine for routine safety tests.
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.
- The study doctor will administer your dose of study treatment (which may be placebo).
- You will have a second electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your dose of study treatment.

Visit 6 (approximately 6 weeks after Visit 3):

You will **not** take your daily morning dose of study treatment on the morning of Visit 6. Instead, you will report to the research center early in the morning following a 10-hour fast. The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down. Your weight and waist circumference will be measured.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will give approximately 6 teaspoons of blood for various tests, including routine safety tests.
- You will provide urine for routine safety tests.
- You will be provided with your daily dose of study treatment.
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.
- The study doctor will review how well you complied with dosing instructions and dispense more study treatment. You will be asked to return any unused study treatment at each visit.

Visit 7 (approximately 8 weeks after Visit 3):
You will **not** take your daily morning dose of study treatment on the morning of Visit 7. Instead, you will report to the research center early in the morning following a 10-hour fast.

The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- The study doctor will review how well you complied with dosing instructions.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down. Your weight and waist circumference will be measured.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your dose of study treatment.
- You will give approximately 6.5 teaspoons of blood for routine safety tests. You will provide approximately 1 teaspoon of blood for pharmacokinetic (PK) analysis prior to receiving your daily dose of study treatment and again approximately 4 hours after receiving your daily dose.
- You will provide urine for routine safety tests.
- The study doctor will administer your dose of study treatment (which may be placebo).
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.

Telephone Call Visit 8 (approximately 10 weeks after Visit 3):
Instead of visiting the research center, the study doctor will contact you to discuss the following:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.

Visit 9 (approximately 12 weeks after Visit 3):
You will **not** take your daily morning dose of study treatment on the morning of Visit 9. Instead, you will report to the research center early in the morning following a 10-hour fast.

The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will have a routine physical examination, including weight, and waist circumference.

- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your dose of study treatment.
- You will give approximately 7 teaspoons of blood for various tests, including routine safety tests.
- You will provide urine for routine safety tests.
- You will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver. This may be scheduled to occur up to 1 week prior to Visit 9.
- The study doctor will administer your dose of study treatment (which may be placebo).
- You will begin 24-hour Holter Monitoring 2 hours before receiving your dose of study treatment. This small monitor is connected by small leads and measures the electrical activity of your heart. You will visit the clinic the following day to return the monitor. You will also be provided with a Holter diary to record comments.
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.
- The study doctor will review how well you complied with dosing instructions.

Visit 9a (24 hours after Visit 9):

- You will visit the clinic only to return the Holter monitor and the diary card.

PART 3 – FOLLOW UP:

Follow-Up (Visit 10, approximately 16 weeks after Visit 3):

You will report to the research center early in the morning following a 10-hour fast. The following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will have a routine physical examination, including weight and waist circumference.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart.
- You will give approximately 6.5 teaspoons of blood for various tests, including routine safety tests and pharmacokinetic (PK) analysis.
- You will provide urine for routine safety tests.
- You will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver.
- You will be asked about any pain or side effects you may be experiencing or have experienced.
- You will be discharged from the study.

Early Exit:

If for any reason you are enrolled into the study and then discontinue the study prior to the planned discharge at Visit 9, (either by your choice or at the study doctor's discretion), the following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will have a routine physical examination, including weight, and waist circumference.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart approximately 4 hours after your dose of study treatment.
- You will give approximate 7 teaspoons of blood for various tests, including routine safety tests.
- You will provide urine for routine safety tests.
- You will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver.
- You will begin 24-hour Holter Monitoring 2 hours before receiving your dose of study treatment. This small monitor is connected by small leads and measures the electrical activity of your heart. You will visit the clinic the following day to return the monitor. You will also be provided with a Holter diary to record comments.
- You will be asked about any side effects you may be experiencing or have experienced since your last visit.
- The study doctor will review how well you complied with dosing instructions.

You will be asked to return in 4 weeks for a final follow-up safety visit in the morning following a 10-hour fast. During that visit, the following will take place:

- You will be asked to review the medications or vitamins you are currently taking (prescribed or over the counter.)
- You will be asked about your lifestyle habits, including alcohol intake.
- Your vital signs (blood pressure and heart rate) will be measured. Blood pressure and heart rate will each be measured three times while sitting down.
- You will have a routine physical examination, including weight and waist circumference.
- You will be assessed for any signs or symptoms that may be suggestive of hyperthyroidism.
- You will have an electrocardiogram (ECG) which measures the electrical activity of your heart.
- You will give approximately 6.5 teaspoons of blood for various tests, including routine safety tests and pharmacokinetic (PK) analysis.
- You will provide urine for routine safety tests.
- You will have an MRI (magnetic resonance image) of your liver to estimate the amount of fat in your liver.

- You will be asked about any pain or side effects you may be experiencing or have experienced.
- You will be discharged from the study.

STUDY PROCEDURES:

Blood Sample Requirements:

Over the course of the entire research study, you will have approximately 58 teaspoons (approximately 1 ¼ cups) of blood collected. For comparison, a standard blood donation is about 2 cups.

The most blood you will give in one day is approximately 7 teaspoons. You may need to return for additional unexpected visits or additional laboratory tests that may require additional blood draws. No genetic or DNA testing will be done on these samples. Tests performed with your blood may include the following:

- **Routine safety tests**: Routine bloodwork provides information about your overall health and includes blood cell counts as well as information about metabolism and chemical balance.

Urine Sample Requirements:

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.

Excluded Activities and General Restrictions:

- You must not consume alcohol 48 hours before receiving your first dose of study treatment, or more than 2 drinks a day of alcohol during the entire study period until your final visit.
- You should not take any acetaminophen containing medications during the study.
- You will not be able to participate in the study if you have donated blood or blood products within 56 days before the screening visit.
- You will not be able to participate in the study if you have a positive history of human immunodeficiency virus, hepatitis B, or hepatitis C.
- You will not be able to participate in the study if you have a history of an MI (myocardial infarct / heart attack) or PCI (percutaneous coronary intervention/ angioplasty) within 1 year of screening or any history of CABG (coronary artery bypass graft / bypass), uncontrolled diabetes or unstable angina.
- You will not be able to participate in the study if you have participated in any clinical study with an investigational drug, biologic, or device within 4 weeks prior to the Screening visit.
- You will not be able to participate in the study if you have participated in a previous clinical study of VK2809.
- You will not be able to participate in the study if you have a documented sensitivity to any of the ingredients in VK2809.

- You will not be able to participate in the study if you have a history of severe allergies (i.e., anyone with a known history of anaphylaxis to medication[s] or allergens and/or asthma requiring hospitalization).

YOUR RESPONSIBILITIES IN THE STUDY:

Taking part in a research study can be an inconvenience to your daily life. Please consider the study's time commitments and responsibilities as a research subject when you are deciding to take part. If you participate in this study, you will not be allowed to join other clinical trials at least until all the follow-up visits for this study are completed. Depending on your condition, you may also have to visit the study doctor for additional visits. Your responsibilities as a study subject include the following:

- To provide, to the best of your knowledge, complete information about your current medical condition and past medical history, including current illness, prior hospitalizations, allergies, and all other health-related matters.
- To tell the study doctor about your medications and any changes in your medications. These include prescription medications, over-the-counter medications, vitamins/minerals, and herbal supplements.
- To discuss the study Treatment Period with the study staff before indicating your agreement to take part in the study by signing this Informed Consent form.
- To comply with the study, to cooperate with study staff, to ask questions if directions or procedures are not clear, and to participate in your health-care decisions. You may withdraw from the study for any reason, but it is desirable to discuss your concerns with the study doctor and study staff before taking that action.
- To report on time for scheduled visits. If unable to do so, you have the responsibility of notifying the study staff and canceling and rescheduling the appointment.
- To report promptly to the study staff any unexpected problems or changes in your medical condition.
- To inform the study doctor or study staff of any concerns or problems with the care and treatment that you feel are not being adequately addressed.
- To provide complete information so that contacts and communications to schedule visits and monitor health status can be maintained. This information should include: (1) your current address and phone number; (2) the names, addresses, and phone numbers of next of kin or persons to be notified in the event of an emergency; and (3) the names, addresses, and phone numbers of physicians responsible for your ongoing care, including your family physician and the physician(s) who referred you to the study.
- To tell the study doctor if you have been in a research study in the last 30 days or are in another research study now.

RISKS OF THE STUDY:

There may be adverse events or side effects that are currently unknown and it is possible that some of these unknown side effects could be permanent, serious or life threatening. The study doctor will inform you of any significant new information that is discovered during the course of this research study. It is your responsibility to share with the doctor any new, increasing, or unusual symptoms you experience while participating in this study.

If you experience any new or unusual symptoms while participating in this study, please seek medical care immediately. Notify the study doctor and study staff as well as your primary care physician.

Risks of VK2809 (i.e., study treatment):

Two clinical studies to evaluate VK2809 have been completed to date. In these two studies combined, 112 subjects have received at least one dose of VK2809 or placebo. In the first clinical study, 56 healthy volunteers (42 receiving VK2809 and 14 receiving placebo) received a single VK2809 dose of up to 50 mg. In the second clinical study, 56 subjects (42 receiving VK2809 and 14 receiving placebo) with mild hypercholesterolemia received a single VK2809 dose of up to 40 mg once daily for 14 days (14 doses of drug).

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 not been reported in subjects who received the placebo. In the first clinical study in healthy volunteers (described above), 3 (7%) subjects had an elevation in either ALT or AST liver function test levels. In the second clinical study in subjects with hypercholesterolemia (described above), 10 subjects (24%) experienced an increase in either ALT or AST liver function test levels. The increased ALT and/or AST returned to normal levels either with continued drug treatment or after the treatment period ended. Most of these elevations were considered mild elevations. You will be monitored with blood tests to look for any increase in your liver function test levels.

Other side effects reported that occurred at least twice during these studies are listed below. This drug may cause some, all, or none of the side effects listed below.

- In the first clinical study with healthy volunteers, side effects reported more than twice in subjects who received VK2809 included nausea (2 events), increased total bilirubin (a substance made in the liver), a blood test (4 subjects), and dizziness (2 events).

- In the second clinical study in subjects with hypercholesterolemia (high cholesterol), side effects reported more than twice in subjects who received VK2809 included eye disorders (2 subjects), eye irritation (2 subjects), chest pain (4 subjects), fatigue (extreme tiredness) (3 subjects), urine discoloration (2 events), dizziness (3 events), headache (8 events), paresthesia (burning or prickling sensation) (2 events), anxiety (3 subjects), insomnia (inability to sleep) (7 events), cough (2 events), and nasal congestion (2 events).

Potential risks are side effects seen in studies of VK2809 in animals or side effects that may occur based on known properties of this type of drug. It is not known if VK2809 causes any of these symptoms in humans. You should always tell your study physician about new, increased or unusual symptoms you are experiencing, including any symptoms similar to the symptoms listed below.

These 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, diastolic hypertension.
  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.

You will be monitored with heart tests to look for any cardiac side effects. 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.

Development of a different drug that is similar to VK2809 was halted due to the observation of cartilage damage in dogs after 12 months of therapy. This side effect has not been observed with limited exposure in humans to date.

Pancreatitis which can be serious and life threatening has been reported in **mice**. It has **not** been reported in humans to date. Please notify the PI if you have any abdominal pain, nausea, vomiting or fever or any unusual symptoms.

It is also possible for VK2809 to interact with and change the blood levels of other drugs. VK2809 is already known to affect the blood levels of oral diabetes drugs including hypoglycemic agents and sulfonylureas, and blood thinners such as warfarin. 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. Some drugs such as ketoconazole and rifampin are already known to affect blood levels of VK2809, so you will be asked not to take these drugs during the study. 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.

Other Risks:

- The ECG leads (small stickers with adhesive on them that are attached to your body) infrequently may cause redness, itching, or mild pain on your skin.
- There is the risk of serious and/or life-threatening side effects when a non-study drug is taken with the study treatment. For your safety, you must tell the study doctor or nurse about all the drugs you are taking before you start the study and before taking any non-study drug while you are in the study. You should also check with your study doctor or nurse before participating in any other clinical trials.

Blood Draw Risks:

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.

Pregnancy risks:

You cannot be in this study if you are a female of childbearing potential, pregnant or nursing a baby.

Since no adequate and well-controlled studies of the study drug [VK2809] in pregnant women or women nursing their baby have been done, you should not become pregnant or nurse a baby while in this study. If you think you are pregnant during the study, you must stop the study drug and tell the study doctor immediately. You should also notify your primary care physician. If you become pregnant, you will have to leave the study. Your doctor may follow the pregnancy until completion or until pregnancy termination. If you are a male, you should not father a baby or be a sperm donor while in this study. In addition, you should not take part in this research if your female partner is currently pregnant or wanting to become pregnant in the period from now until 28 days after your exposure to the last dose of study drug. It is required that all sexually active male patients use one of the following methods of contraception during the trial and for 28 days following their final study drug dose:

1. Abstinence.
2. Use of condom for males with a vasectomy.
3. Male patients, without a vasectomy, must use a condom and be instructed that their female partner should use another form of contraception such as an IUD, spermicidal foam/gel/film/cream/suppository, diaphragm with spermicide, oral contraceptive, injectable progesterone, subdermal implant or a tubal ligation if the female partner could become pregnant. This requirement must be followed from the time of the Week 1 dose of study drug until 28 days after the last dose of VK2809.

Unknown Risks:

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems. If you have a serious side effect, the study team may take you out of the Study.

The study team will tell you if any important new risks become known during the course of this study that may impact your decision to continue participation.

ALTERNATIVES TO BEING IN THE STUDY:
Since this study is not intended to provide treatment. It is not necessary for you to be enrolled in this study. An alternative to participation in this study is not to participate.

POTENTIAL BENEFITS OF BEING IN THE STUDY:
You may or may not receive medical benefit from participation in this study. The information gathered from this study may help in the future treatment of patients who have high cholesterol and fatty liver disease. If new information, either good or bad, about this research develops during the course of this study that may cause you to change your mind about continuing in this study, it will be promptly provided to you or your representative.

PAYMENT AND EXPENSES:
The study treatment, office visits (including the research center admittance), medical tests and procedures that are part of the research study that are not standard of care will be provided at no cost to you or your insurance agency.

WHAT COMPENSATION WILL YOU RECEIVE IF YOU PARTICPATE IN THIS STUDY?
You will be compensated for each study visit according to the following breakdown:

Visits:	**Compensation Amount:**
Visit 1: Screening	$50.00
Visit 1a: Holter Monitor Return	$50.00
Visit 2: Week -8 to Week -6	$50.00
Visit 3: Week 0	$100.00
Visit 3a: Holter Monitor Return	$50.00
Visit 4: Week 1	$100.00
Visit 4a: Holter Monitor Return	$50.00
Visit 5: Week 4	$100.00
Visit 6: Week 6	$50.00
Visit 7: Week 8	$100.00
Visit 8: Week 10 Phone Call	$00.00
Visit 9: Week 12	$100.00
Visit 9a: Holter Monitor Return	$50.00
Visit 10: Week 16	$50.00
Potential Total	**$900.00**

You will only be compensated for the study visits you complete. If you withdraw from the study or are dropped from the study due to circumstances beyond your control, such as medical reasons, or technical problems, you will receive a pro-rated compensation based on the study visits that you have completed.

PAYMENTS TO STUDY SITE:
The study Sponsor, Viking Therapeutics, Inc., is paying Integrium, LLC for the work performed by the study doctor and study staff in this study.

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 Sponsor to be a direct result of your receipt of 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 or any medical condition you may have had before receiving study treatment except to the extent exacerbated 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 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 by signing this form. Should you require further information about compensation and treatment for injury, you should talk with the study doctor.

CONFIDENTIALITY:
Your doctor will record your study information on forms that will be sent to the study Sponsor, Viking Therapeutics, Inc. The study Sponsor will use the information to support new or existing approvals for medical use of the study medication. Authorized persons employed by the Sponsor, FDA or other governmental regulatory agencies, and Aspire Independent Review Board (IRB) may need to look at your medical records to verify the information. By signing this informed consent form, you agree to allow this review of your records.
All records in which your name appears will be kept confidential. Your name will never appear on any Sponsor forms, or in a report or publication.

The study site will also transfer to Viking Therapeutics, Inc. some of the information it collects, in a coded form.

The information transferred will not include your name, address, or other direct identifiers. It will be assigned a code number that only the site can connect back to your name.

Your permission to the doctor and staff to use this information or share it with Viking Therapeutics, Inc. and others as described below for the study doesn't automatically end at a particular time.

Medical information about you may be produced as part of the research or study procedures. If at the time of the study, this information is known to be relevant to your medical care it will be given to the doctor who will be encouraged to share it with you or your regular doctor.

While you are in the study, however, the study site will not share certain new medical information about you that is created as part of the study (such as whether or not you are getting study drug, or the results of certain tests) unless the doctor decides it is medically important to do so. This is done to stop the study results from being distorted. Once the study is over, you will be given access to medical information about you that you are entitled to see.

You will be told if any of this medical information requires confirmation using a clinical test. This is important because some research results are for research purposes and may have only limited relevance for clinical diagnosis or treatment. At any time, you may ask your doctor to let you see your personal information, e.g. name and address and to correct it if necessary.
By signing this form, you agree to the use of your personal data for the purpose described in this form and to the transfer of your data to other countries in accordance with national laws on the processing of personal data.

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.

In the rare event that your information is required to be disclosed by law to another entity, privacy laws may not apply, and neither the Sponsor nor Aspire IRB can protect your information.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY:
You can ask questions about this informed consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Any payment for being in the study;
- Your rights and your responsibilities as a study subject;
- Any other questions.

Contact the study doctor or study staff with any questions, concerns or complaints. Their telephone number is printed on the first page of this form.

This study was reviewed by Aspire Independent Review Board (IRB). An IRB reviews research to protect the rights and welfare of study participants.

If you have questions, concerns, complaints and/or for information about your rights as a research subject, please call Aspire's Study Participant Advocate at 1-877-366-5414 (toll free).

Although Aspire IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean Aspire has approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

BEING A STUDY VOLUNTEER:
Entering into this research study is voluntary.

- You may always say no. You do not have to take part in the study or study procedures.
- If you start this study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in this study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you. There may be additional tests, exams or procedures required for you to exit the study safely.

You may decide to withdraw from the research study at any time by providing notification of your decision to the study doctor. However, researchers may continue to use data previously collected from you before you withdrew from the research study.

Your part in the research may also be stopped by your study doctor, the Sponsor or the FDA at any time, with or without your consent for any reason, such as:

- The Sponsor, the FDA or the study doctor decides to stop the study.
- The Sponsor or the study doctor decides to stop your participation in the study for your safety.
- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You have an adverse reaction to the study treatment.

YOU MAY BE ASKED TO STOP THE STUDY EVEN IF YOU DO NOT WANT TO STOP.

NEW INFORMATION ABOUT THE STUDY:
If new information, either good or bad, develops during the course of this study that may cause you to change your mind about continuing in this study, it will be promptly provided to you or your representative.

STATEMENT OF CONSENT:
I have read this form and its contents were explained to me. I voluntarily agree to be in this research study for the purposes listed above. I have been told that I can change my mind later if I want to. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT:
I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____
Signature of Person Explaining Consent Date

_____
Printed Name of Person Explaining Consent

HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

During your participation in this research study, the study doctor and staff will collect personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the protocol) and record it on protocol documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your study records, information regarding your past, present and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your regular physician. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". You may refuse to sign this Authorization; however you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI as collected or created in your study records to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose your Study records as described below:

- The Sponsor of this protocol and anyone working on behalf of the Sponsor to conduct this study or analyze the results of the study. The Sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a unique identification number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The Sponsor may, however, look at your complete study records that identify you. In addition, the Sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.
- The Aspire Independent Review Board ("IRB"), which may have access to your PHI in relation to its responsibilities as an Independent Review Board.

The study doctor or Sponsor may disclose your PHI to the United States Food and Drug Administration (FDA) or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

Except for the disclosures described above, your PHI will not be shared with others unless required by law.

If your PHI is given to the parties listed above and/or to others who are not required to comply with the Privacy Rule, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the Sponsor has completed all work related to this study. At that time, you may ask to see your records.

Unless you live in California, this Authorization will expire upon your written request to revoke it as described below. If you live in California and do not submit a written request to revoke your Authorization, then this Authorization will expire 50 years from the date that you sign this form.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research Study. To revoke your Authorization, you must write to the study doctor at the address provided on the first page of this consent form, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this research study.

You may choose not to sign this HIPAA form. However, you will not be able to take part in the study without signing. You will receive a signed and dated copy of this Authorization after you have signed it.

STATEMENT OF AUTHORIZATION:

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

_____ ____/____/____

Signature of Research Subject Date

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING AUTHORIZATION:

I have carefully explained to the subject the nature and purpose of this form. I have been available to answer any questions that the subject has about this form.

_____ ____/____/____

Signature of Person Explaining Authorization Date

_____

Printed Name of Person Explaining Authorization