INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**LIB Therapeutics, LLC. / "Randomized, Double-Blind, Placebo-Controlled, Phase 2, Dose-Finding Study to Evaluate the Efficacy and Safety of LIB003 in Patients on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction"**
Protocol Number:	**LIB003-002**
Principal Investigator: (Study Doctor)	**«PiFullName»**
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Address:	**«PiLocations»**

THE INFORMED CONSENT PROCESS

You are being asked to participate in a clinical research study sponsored by LIB Therapeutics, LLC, the company paying for this study. Before you decide if you want to participate, you need to understand the purpose of the study, the possible risks and benefits, and what is expected of you. This process is called Informed Consent.

This informed consent form will explain to you the purpose and procedures in the study, describe possible discomforts and risks that may occur and describe any possible benefits. This form will also include information about the health information that will be obtained from you, the extent of confidentiality that will be maintained, if there is any compensation and/or medical treatment available to you if injury occurs, and whom to contact if you have any questions about the study or your rights as a research subject. Your participation in this study is entirely voluntary and you have the right to stop your participation at any time.

Please read this form carefully. Take as much time as you need to read this form, to ask the study doctor or study staff questions, to discuss it with your regular doctor, family, friends, and/or anyone you choose before deciding whether or not to participate. If there are any words or information that you do not understand, the study doctor or study staff will explain them to you. Reading this form and talking to the study doctor or study staff may help you decide whether to participate in this study or not. If you agree to participate in this study, you must sign and date this consent form before any study-related tests or procedures are performed. You will be asked to provide consent for the study doctor or study staff to inform your primary-care doctor about your participation in this study.

PURPOSE OF THE STUDY

The study doctor and LIB Therapeutics, LLC, the sponsoring drug company, are conducting this research study of an investigational drug named LIB003 for potentially lowering LDL (low density lipoprotein) cholesterol, which is sometimes called 'bad' cholesterol. Lowering LDL with drugs has been shown to reduce cardiovascular risk. LIB003 is small protein, called an Adnectin, modified from a naturally occurring protein in the body called fibronectin, which has been designed to block PCSK9, a protein in the blood stream that inhibits or reduces the removal of LDL cholesterol which is usually done by the liver. The investigational drug LIB003 in this study is given by injection under the skin. An "investigational" drug is one that has not been approved by the Food and Drug Administration (FDA) for use in the United States, but has been approved for testing in research studies such as this one. You may be eligible to participate in this study because you have increased LDL cholesterol while on diet and taking a statin or other type of cholesterol lowering medication. About 80 subjects will be enrolled in this study in the US which will be the second study in humans of this investigational drug LIB003.

The purposes of this study are:

- To assess the safety and tolerability (how a person's body reacts) to LIB003 when given multiple doses by subcutaneous [SC] (under the skin) injection. LIB003 will be tested in people with increased LDL-C levels either taking a statin medication alone, or ezetimibe (Zetia) alone or both. This assessment will be done by performing a physical exam including vital signs (including heart rate, blood pressure, breathing rate, and temperature), laboratory tests (including blood and urine samples), and electrocardiograms (ECGs). We will also keep track of any side effects subjects might experience.
- To assess, through blood tests, the effect of LIB003 on LDL cholesterol, triglyceride and other related tests.
- To collect information about how the levels of LIB003 and PCSK9 change in subjects' blood over time prior to and after receiving this investigational drug.
- To assess subjects' immune response (to see if their bodies will make antibodies against LIB003) to this investigational drug.

PROCEDURES INVOLVED IN THIS STUDY

This study is a double-blind, randomized study. "Double-blind" means that neither you nor the study doctor will know who is receiving LIB003 and who is receiving placebo (an inactive substance containing no study drug also given by injection under the skin). "Randomized" means that the group you will be placed in is decided by chance from a computer, similar to drawing numbers out of a hat or flipping a coin.

Be aware that this form refers to both LIB003 and placebo as "study drug."

A total of about 80 subjects will be enrolled in this roughly 20 week outpatient study with about 60 subjects randomized to receive LIB003 (SC) and about 20 to receive placebo (SC). There will be three (3) LIB003 dose groups, with each group consisting of about 20 subjects. The three LIB003 groups will receive doses of 150 mg or 300 mg or 350 mg or placebo, which will be given by SC injection every 4 weeks for a total of 3 doses.

The subjects participating in this study include men and women who are 18 years of age or older (women of childbearing potential must be using an effective form of birth control and have a negative pregnancy test at screening) with either previous heart disease (CVD), at high risk for developing heart disease (greater than or equal to 10% in 5 years or greater than or equal to7.5% in 10 years), or inherited high cholesterol (called FH) and also have a LDL-C greater than or equal to 80 mg/dL (CVD or high CVD risk) or greater than or equal to 100 mg/dL (heterozygous familial hypercholesterolemia [HeFH] and no CVD). All subjects must also have triglycerides (TG) less than or equal to 400 mg/dL and be on stable diet and cholesterol lowering medication consisting of a statin or ezetimibe or both. Subjects unable to tolerate statins or approved doses of a statin may take lower than approved doses and less frequently than daily as long the dose and dosing frequency is consistent.

If you are currently taking a statin and/or ezetimibe you will have had to be on a stable (same) dose for 4 or more weeks prior to enrollment in the study and must remain on that dose for the duration of the study.

If you would like to participate in the study you cannot be taking, or have taken, in the last 6 to 8 weeks any other prescription cholesterol lowering drugs, or over-the-counter supplements, or herbal medications such as certain vitamins such as high doses of niacin or fish oils unless approved by the study doctor. Stable doses of hormone replacement therapy which you have been on for 2 or more months prior to the study and will continue throughout the study is allowed as are other chronic medications for treating conditions like diabetes, high blood pressure etc. The study nurse or doctor will review all your medications to make sure they are allowed in this study and inform you if not. You will be excluded from the study if you have previously participated in a study with any other adnectin product, if you have history of allergy to monoclonal antibody and vaccines, if you have history of significant drug allergy, or participated in another clinical study within 1 month prior to screening. You cannot participate if you have donated or lost a significant amount (more than 1 pint) of blood or plasma within 31 days prior to the anticipated start of study drug administration and you cannot donate blood or plasma during the study.

If you qualify for this study, your participation will be for about 20 weeks. After a screening period to assess eligibility of participation, which could be up to 28 days, or as short as 7 days, you will return to receive the 1st dose of LIB003 or placebo by SC injection.

This will be followed by 8 additional outpatient visits at 2 week intervals for the next 16 weeks. The study staff will review all the restrictions and requirements of the study with you to determine if you qualify for the study and to answer your questions.

Blood samples: An important part of this study is the blood samples that will be taken during each of your visits after an overnight 10 hour fast (water will be allowed and encouraged). These blood samples have several different purposes:

1. The samples will be taken to evaluate the safety and effectiveness of the study drug. This will be done by laboratory measurements to see if there are any changes in your blood compared to before you were given the study drug. The changes in LDL cholesterol and other blood fats as well as PCSK9 will be measured.

2. Other samples are being taken to measure the amount of LIB003 in your blood over time (also known as pharmacokinetics or PK).

3. Some samples are being taken to see if your body makes any antibodies to LIB003 (also known as Immunogenicity or anti LIB003-antibodies). Making antibodies is a common reaction by your body to anything foreign in your blood, and it may or may not occur in your body.

4. Some samples may be used to study other proteins in your blood. These samples may also help us to understand how LIB003 is working in the body. Some of these samples may also be stored for future studies of other cholesterol carrying fractions and inflammation.

All of the information that we collect from these samples helps us to better understand the way that your body deals with the study drug, and also any effect that the study drug might be having on your body.

WHAT WILL HAPPEN DURING THE STUDY

Visit 1: Screening Visit

At the Screening Visit, or before, you will be asked to read this informed consent form. If after all your questions have been answered to your satisfaction and you would like to participate in this study, you will be asked to sign and date this form. The following will also occur at this visit:

- A number of questions will be asked about your demographics, medical history and current health status.
- You will be asked some general questions about how you are feeling and about any medications or over-the-counter supplements you are taking. Specific questions will be asked about cholesterol medications such as statins you are, or have been, taking.
- A physical examination.
- Your blood pressure, height, weight, breathing, temperature and heart rate will all be measured.
- An electrocardiogram (a tracing of your heart rhythm) will be done.
- A fasting blood sample will be taken, using a needle to collect blood from a vein in your arm. A total of 19 ml (about 1⅓ tablespoons) of blood will be drawn for the routine clinical tests listed below to determine if you are eligible to participate in the study. The study doctor or study staff will explain this process to you and what will happen based on your test results.
    - Full safety chemistry, hematology, and TSH (Thyroid Stimulating Hormone)
    - Brief lipid panel
    - Serum pregnancy test (for women of child-bearing potential)
- A urine sample will be collected for routine clinical tests.
- If you are a woman and pregnant or breastfeeding, you cannot participate in the study. Women who can have children and are taking an effective form of birth control such as diaphragm or cervical cap with spermicide or intrauterine device, oral, implantable, or injectable contraceptives, or women who can no longer bear children due to a surgical procedure (a hysterectomy, both ovaries removed, or both tubes cut or tied), or are postmenopausal for at least 1 year (if uncertain, a blood test called follicle-stimulating hormone [FSH] with a level greater than 40 mIU/mL must be documented) can participate. To make sure no woman who can have children is pregnant, a pregnancy test will also be done. You must agree to use effective birth control for 90 days beyond the last dose of the study drug.

- If you are a man you will need to be either surgically sterile or agree to use, from the time you start the study drug until 90 days following the last dose of study drug, one of the following forms of contraception: male or female condom with spermicide; a female partner who is sterile or who agrees to use the following contraceptives, diaphragm or cervical cap with spermicide; or intrauterine device (IUD), oral, implantable, or injectable contraceptives. You must also refrain from sperm donation from when you start the study drug until 90 days following the last dose of study drug.

Visit 2: Day 1

You will come to the clinic in the morning so we can review your health and medication history since your previous visit, take fasting (10 hours with only water allowed and encouraged) blood samples, and be randomized to the study drug or placebo. The following will occur at this visit:

- You will be asked some general questions about how you are feeling and about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, weight, breathing, temperature and heart rate will all be measured.
- A fasting blood sample will be taken, using a needle to collect blood from a vein in your arm. A total of 37 ml (about 2.5 tablespoons) of blood will be drawn for clinical laboratory tests listed below.
    - Full safety chemistry and hematology
    - Expanded lipid panel
    - PK
    - PCSK9 (total and free)
    - Immunogenicity
    - Exploratory biomarkers
- A urine sample will be collected for routine clinical tests.
- A physical examination will be done if the previous one done at the screening visit was more than 14 days earlier.
- You will be randomized to study drug and receive the first injection under the skin (SC) in your abdomen a few inches away from the belly button. You will wait at least 15 minutes after the injection to make sure everything is OK.

Visit 3: Day 15

You will come to the clinic in the morning so we can review your health and medication history since your previous visit and take fasting (10 hours with only water allowed and encouraged) blood samples. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects, or health problems since your last visit.
- You will be asked about any medications since the previous visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A fasting blood sample of about 22ml (1.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Brief Safety chemistry panel
    - Brief Lipid panel
    - PK

  - PCSK9 (total and free)
- The SC injection site will be assessed.

Visit 4: Day 29

You will come to the clinic in the morning so we can review your health and medication history since your previous visit, take fasting (10 hours with only water allowed and encouraged) blood samples, and receive the second dose of study drug or placebo. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, weight, breathing, temperature and heart rate will all be measured.
- A urine sample will be collected for routine clinical tests.
- A fasting blood sample of about 37 ml (2.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
  - Full Safety chemistry and hematology
  - Expanded Lipid panel
  - PK
  - PCSK9 (total and free)
  - Immunogenicity
- You will receive the second SC dose of study drug.
- The injection site will be assessed before and 15 mins post-dose.

Visit 5: Day 43

You will come to the clinic in the morning so we can review your health and medication history since your previous visit and take fasting (10 hours with only water allowed and encouraged) blood samples. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A fasting blood sample of about 22ml (1.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
  - Brief Safety chemistry panel
  - Brief Lipid panel
  - PK
  - PCSK9 (total and free)
- The SC injection site will be assessed.

Visit 6: Day 57

You will come to the clinic in the morning so we can review your health and medication history since your previous visit, take fasting (10 hours with only water allowed and encouraged) blood samples, and receive the third dose of the study drug or placebo. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, weight, breathing, temperature and heart rate will all be measured
- A urine sample will be collected for routine clinical tests.
- A fasting blood sample of about 37 ml (2.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Full Safety chemistry and hematology
    - Expanded Lipid panel
    - PK
    - PCSK9 (total and free)
    - Exploratory biomarkers
    - Immunogenicity
- You will receive the third SC dose of study drug.
- The injection site will be assessed before and 15 mins post-dose.

Visit 7: Day 71

You will come to the clinic in the morning so we can review your health and medication history since your previous visit and take fasting (10 hours with only water allowed and encouraged) blood samples. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A fasting blood sample of about 22ml (1.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Brief Safety chemistry panel
    - Brief Lipid panel
    - PK
    - PCSK9 (total and free)
- The SC injection site will be assessed.

Visit 8: Day 85

You will come to the clinic in the morning so we can review your health and medication history since your previous visit and take fasting (10 hours with only water allowed and encouraged) blood samples. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- You will be weighed and have a physical examination.
- You will have a 12-lead ECG.
- Your blood pressure, breathing, temperature, and heart rate will be measured.
- A urine sample will be collected for routine clinical tests.

- A fasting blood sample of about 37 ml (2.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Full Safety chemistry and hematology
    - Expanded Lipid panel
    - PK
    - PCSK9 (total and free)
    - Immunogenicity
    - Exploratory biomarkers
- The injection site will be assessed.

Visit 9: Day 99

You will come to the clinic in the morning so we can review your health and medication history since your previous visit and take fasting (10 hours with only water allowed and encouraged) blood samples. The following will occur at this visit:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A fasting blood sample of about 22 ml (1.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Brief Safety chemistry panel
    - Brief Lipid panel
    - PK
    - PCSK9 (total and free)
- The SC injection site will be assessed.

Visit 10: Day 113/Early Termination Visit

This is the final visit for everyone completing the entire study or for subjects who are withdrawn early from the study prior to completion of all other 9 visits. At this visit you will have the following performed;

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- You will be weighed.
- If you are terminating the study early you will have a physical examination.
- If you are terminating the study early before visit 8 you will have a 12-lead ECG.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A urine sample will be collected for routine clinical tests.
- A fasting blood sample of about 37 ml (2.5 tablespoons) will be taken, using a needle to collect blood from a vein in your arm for the following tests:
    - Full Safety chemistry and hematology
    - Expanded Lipid panel

  - PK
  - PCSK9 (total and free)
  - Immunogenicity
  - Exploratory biomarkers
- If you are a woman of childbearing potential you will have a pregnancy test.
- The injection site will be assessed.

Follow-up Visit for subjects who develop positive antibodies to the study drug

If you develop positive antibodies to the study drug and they are associated with clinical symptoms that are considered safety related at final visit (week 16) you may be asked to return for additional monthly follow-up testing.

If you develop antibodies that are known as neutralizing antibodies, which then prevent the study drug from working properly at the final visit (week 16) you will be asked to return for follow‑up testing every 3 months until either these antibodies are no longer detectable or you have been followed for a period of at least 12 months. For subjects who test positive but have not received active drug follow-up testing will not be required.

The following procedures will be performed at the follow up visits:

- You will be asked some general questions about how you are feeling, side effects or health problems since your last visit.
- You will be asked about any medication you have taken since your last visit including statin, statin dose and/or ezetimibe plus adherence.
- You will be weighed.
- Your blood pressure, breathing, temperature and heart rate will be measured.
- A urine sample will be collected for routine clinical tests.
- A fasting blood sample of about 22 ml (1.5) tablespoons will be taken, using a needle to collect blood from a vein in your arm for the following tests:
  - Full Safety chemistry and hematology
  - Brief Lipid panel
  - PCSK9 (total and free)
  - Immunogenicity.
- The injection site will be assessed.

A total of about 19 tablespoons or 1.25 cup of blood will be taken from you during this study (Screening period through End-of-Study Visit). For comparison, the standard blood donation of 1 unit, is about 32 tablespoons or 2 cups, and may be donated every eight weeks.

DISCOMFORT AND RISK

This is the second study in humans with LIB003. It is the first study in which subjects with CVD or high risk of CVD and high cholesterol on statins or ezetimibe or both will receive multiple doses of LIB003.

Placebo Risks

Subjects assigned to placebo will not be anticipated to have any risks other than that possible from the SC injection which may cause pain and swelling. However, receiving placebo is the

same as not taking any additional medication other than the statin or ezetimibe or both for your increased cholesterol. Your symptoms may not improve or get worse. Please ask the study doctor or study staff if you have any questions about placebo.

Risks Associated with LIB003

LIB003 is not marketed in any country. There has been one previous clinical (human) study with LIB003 where both normal volunteers or patients taking statins with LDL-C greater than or equal to 100 mg/dL and less than or equal to 190 mg/dL received a single dose of LIB003. A total of 45 study subjects received LIB003 at doses ranging from 25 mg to 600 mg and the study drug was given SC at all doses, except for 2 groups that received the 300 mg and 600 mg dose intravenously (IV – directly into a vein). Each study subject was observed in an inpatient unit for 3 days after receiving the study drug and then as outpatients for at least 6 weeks (43 days) after receiving the study drug. LIB003 was well tolerated, no study subject either on LIB003 or placebo experienced injection site reactions such as rash, redness, itching or swelling. One study subject experienced swelling of his lips after 2 days which decreased after a few days and was treated with an oral antihistamine medication. A total of 6 of 18 (33%) placebo subjects and 13 of 45 (29%) LIB003 subjects none of these were considered serious or study drug related.

The most common adverse events (side effects) reported by more than 1 subject were respiratory infections, gastrointestinal, eye (blurred vision), Central nervous system (CNS [headache]) and musculoskeletal; all other adverse events were reported by 1 subject only. None appeared dose related or more frequent in LIB003 treated subjects compared to placebo. One subject on the lowest dose, 25 mg, of LIB003 developed a low level of antibodies to LIB003 but this was not associated with any clinical or laboratory side effects. A second subject who received 600 mg IV of LIB003 developed an antibody response after 3 weeks, which became progressively more positive, with higher levels by Day 43. The subject is still being followed at monthly intervals until the antibodies become negative or are deemed stable. There were no associated clinical or laboratory adverse effects and there did not appear to be any neutralizing antibodies as LDL-C reduction, which extended past 6 weeks, did not appear lower compared to other subjects treated with LIB003 with the same dose of LIB003.

Study subjects will receive no known health benefit from participating in this study. A large amount of information in people with naturally occurring very low levels of PCSK9 and for two other drugs similar to LIB003 which block PCSK9 and are now marketed show no side effects or toxicity.

Single and multiple dose toxicity studies of LIB003 were conducted in cynomolgus monkeys to assess the overall potential risk of exposing human subjects. The highest doses tested in these monkey studies were more than 20-fold higher than the highest doses planned in this human study. There were no adverse findings. Thus, the overall safety profile of LIB003 in monkey studies supports evaluation of the safety and tolerability of the doses of LIB003 to be used in this study in human subjects.

Like other drugs that may suppress the function of PCSK9, LIB003 has theoretical risks associated with suppression of your immune system, although none of these have been found with other drugs, such as monoclonal antibodies, which inactivate PCSK9. If your immune system is suppressed significantly, you may be more susceptible to infections and if this occurs over long periods even cancer. Additionally, like other anti-PCSK9 compounds, LIB003 has the theoretical risk of causing liver injury, colon cancer, and increased susceptibility to hepatitis C

virus infection, although none of these have been found with current approved and marketed drugs approved to inactivate PCSK9. In this study, you will be given a single dose of LIB003. Any potential effect of the study drug is expected to be temporary and insufficient to cause lasting impairment of your immune system, liver function, or susceptibility to hepatitis C.

The study drug will be given by subcutaneous (under the skin) injection into the abdomen. This may cause pain, discomfort, bruising, dizziness, infection, or irritation.

Allergic Reaction Risks

Sometimes, people have serious allergic reactions to drugs. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include rash, difficulty breathing, coughing, wheezing, sudden drop in blood pressure, swelling of the mouth, throat or eyes, seizures, flushing, fainting, a fast pulse, and sweating. If you believe you are having a serious allergic reaction, you should seek emergency medical treatment immediately and alert the study doctor and study staff as soon as possible. You will be under observation for at least 15 mins in the clinic after you have received the study drug should any of these side effects occur.

Some people may experience irritation at the injection site or even an allergic reaction to the study drug. You may have a reaction at the site of the injection which can be mild to severe and painful. The study staff will treat either of these conditions if they should occur.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Be sure to tell the study doctor and/or study staff about any changes to your health during the study, including but not limited to any of the side effects described here.

Unknown Risks

It is possible that there will be other side effects associated with LIB003 that are unknown at this time, including serious, life-threatening, and even fatal side effects. You should tell your study doctor or a member of the study staff about any new health problems that develop while you are in this study and about any new medications you start taking (including nonprescription, over-the-counter medication).

Statin and Ezetimibe Risks

Statins and ezetimibe are approved drugs for the treatment of elevated LDL cholesterol and have been prescribed by your doctor unrelated to this study. The products labeling describes two important risks (potential damage to muscle tissue and/or to the liver). Large and long term studies with patients taking statins and/or ezetimibe have shown no increased side effects when combined with drugs which inhibit PCSK9.

Reproductive Risks

The effects of LIB003 on an unborn baby or nursing (breast feeding) infant are unknown. It is possible that the use of LIB003 may be associated with unanticipated risks to a pregnancy or fetus.

Female subjects who can become pregnant must use an effective form of birth control such as diaphragm or cervical cap with spermicide or intrauterine device, oral, implantable, or injectable contraceptives, or women who can no longer bear children due to a surgical procedure (a hysterectomy, both ovaries removed, or both tubes cut or tied).

Male subject options include male or female condom and spermicide, and a female partner who is sterile or who agrees to use the following contraceptives; diaphragm or cervical cap with spermicide; or intrauterine device, oral, implantable, or injectable contraceptives; or a vasectomy. Male subjects must also refrain from sperm donation until 90 days following the last dose of the study drug.

If you are a man, you must avoid getting a woman pregnant during the study. If you think that you have gotten a woman pregnant, you must tell the study doctor at once.

Both male and female subjects must use effective contraception during the entire time of taking the study drug and for 90 days after the last dose of study drug.

If you or (for men) your partner gets pregnant during the study, the expectant mother will be asked to provide additional consent for release of information to follow the pregnancy, any complications, and the health of the baby. The study doctor or study staff may share this information with the sponsor and Advarra (study IRB) (a group of people who review research studies to protect the rights and welfare of research participants). If additional follow-up is necessary, the study doctor will inform you of the necessary procedures.

PROCEDURE-RELATED RISKS

Risks Associated with Blood Draws

Your blood will be drawn by individual needle sticks, it is possible that more than one try may be needed to get enough blood. The total amount of blood to be drawn at all of the study visits is about 290 mL, which is about 1.25 cups. That is a little more than half the amount of blood that would be drawn if you donated a unit of blood at a blood bank.

Risks related to drawing blood may include discomfort, swelling, bruising, infection, bleeding, pain, lightheadedness, and/or redness at the site of the needle stick. If you feel faint, tell the study staff right away.

ECG Risk

Electrocardiograms (ECGs) will be done during this study. An ECG is a tracing of your heart's electrical activity and is used to look at the pattern of your heartbeat and detect abnormalities of the heart's action. The procedure requires having small wires attached to your body (using small adhesive patches) in several places. Each ECG will take about 15 minutes to complete.

You may experience temporary discomfort (pulling on the skin/skin hair) during removal of the patches. Male subjects may require having their chest shaved for the ECG.

Fasting Risks

You will be asked to fast overnight (no food or liquids except water which you are encouraged to drink) for at least 10 hours before coming to the study clinic. Fasting may cause dizziness, headache, stomach discomfort, or fainting.

If you feel faint, you should tell the study staff right away.

Confidentiality

There is a risk of loss of confidentiality of your information that is used in this study. You will read more about the protection of your information later in this form. Please ask the study doctor

or study staff if you would like to know more about how your information will be protected while you are in this study.

NEW INFORMATION ABOUT THE STUDY

The information in this form reflects what is known about the research study at the time it is signed and dated. If any new information is discovered during the research study that may affect whether you want to continue to take part in the study, you will be informed.

POTENTIAL BENEFITS FROM STUDY PARTICIPATION

Being in this study will not help you. Your participation in this study may add to the scientific data related to the treatment of high cholesterol and may potentially help others in the future.

ALTERNATIVE TREATMENT

There are approved therapies for treating high cholesterol which include different or higher doses of statins than what you are currently taking. The risks for each statin is outlined in the product's labeling which describes two important risks/side effects of potential damage to muscle tissue and/or to the liver.

Other cholesterol lowering drugs include ezetimibe, which you may or may not already be taking, and which works differently than statins and has fewer potential side effects.

There are also two approved drugs which inhibit PCSK9, called evolocumab (Repatha) and alirocumab (Praluent) which are given by injection every 2 weeks and lower LDL cholesterol and have been shown to reduce heart disease. Both are generally well tolerated with the main side effects related to injection site reactions.

The study doctor can discuss these treatment options with you. In addition, you may discuss your options with your regular health care provider.

CONFIDENTIALITY OF PERSONAL INFORMATION

Collection of Study Data

Your study doctor and study staff will collect information about you which is relevant to this study, specifically information about your name, address, contact details, date of birth, medical records, health, your race, ethnic origin and your life habits and sexual life. This collected information about you is called "data" or "study data" in this document.

Records, created by a doctor or hospital as part of your medical care, are called medical records. Records created by a research study are called research records. The records that will be collected, used, and shared for this study may include your research records, supporting information from your medical records, results of laboratory, diagnostic or other tests, results of tests on samples (blood or urine,) that have been stored, and clinical and research observations made during your participation in the research study.

As part of this study, the study doctor and staff will record health information about you that contains your name and other personal identifiers. Authorized representatives of LIB Therapeutics, LLC or its business partner, Medpace, in the research study, the Food and Drug Administration (FDA), the IRB, a group that looks out for the rights and welfare of research subjects, other US government agencies, and possibly government agencies of other countries,

will be given access to these records at their request and may copy them. Copies of the study records that do not include your name but may be traced back to you may be given to LIB Therapeutics, LLC and laboratories working with the sponsor on this study. The sponsor may send a copy of the records to government regulatory agencies as required by law.

Absolute confidentiality cannot be promised because information needs to be shared as described above. However, information will be collected and shared following professional standards of confidentiality.

Information and results from this study may be presented at meetings or published in journals. Your name and information that can easily be traced back to you will not be included in any presentation or publication.

For your safety, the study doctor should tell your regular care provider that you are in this study if the study doctor is not your regular care provider. Please discuss any concerns about this with the study doctor.

A description of this clinical trial may 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.

Confidentiality of Study Data and Key-coded Data

For the purposes of your participation in this study and the protection of your identity, your study doctor will assign you a unique code, such as a series of numbers and/or letters. The study doctor will record the study data collected from you in a report form that uses your assigned code, not your name. This is to protect your study data by making it anonymous for most study purposes.

The data that is recorded with your assigned code rather than your name is called **"key-coded data"**. The key-coded data will be entered into the study's computer database. Your study doctor will keep a confidential list linking your name to your code and only authorized persons will have access to this list. The ways in which key-coded data may be used and shared is described below.

Some study data will identify you (such as medical records), and the ways in which this data may be used and shared is described below.

Use and Sharing of Key-Coded Data

Your key-coded data may be shared with and used by the following:

- The study doctor and study staff
- The study sponsor, its current or future research partners, collaborators, assignees, licensees or designees and their affiliates, agents, and employees
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories and study sites (in the event you transfer to another study site);
- Domestic or foreign health authorities e.g., the Food and Drug Administration (FDA)
- Advarra or other persons required by law

Your key-coded data will be used in connection with this study and may also be:

- used for other current or future research involving the same study drug, the same or related health conditions, or for other relevant health research;
- transferred to individuals or companies located outside of the country or region in which you reside. However, all access to the key coded data will be controlled in accordance with applicable laws and regulations. This may include written agreements that require that the data be kept confidential and secure and be used only for the purposes permitted by this consent form or applicable laws and regulations;
- used in publications about this study but it will remain coded. Your identity will not be revealed in any compilation, study report or publication at any time.

Use and Sharing of Study Data that Identifies You

The use and sharing by your study doctor of study data that identify you, such as your original medical records, are explained in a separate Health Insurance Portability and Accountability Act of 1996 (HIPAA) Authorization at the end of this form. By signing the HIPAA Authorization, you show that you give permission for the uses and sharing of this data as described in the HIPAA Authorization. You do not have to sign the HIPAA Authorization, but if you do not, you will not be allowed to participate in this study. To withdraw your HIPAA authorization, you will need to do so in writing.

Your Access to and Correction of Study Data that Identifies You

You have the right to obtain any initial and updated information about the study data that identifies you, as well as the right according to local law and procedures to require the correction of any errors.

This information, as well as the fact of your participation in this study, can also be provided or made known to your primary physician if you wish.

You can discuss this further with your study doctor, who will be your primary contact person for your access rights.

Use and Collection of Study Data If You End Study Drug Dosing or Withdraw From the Study

When you stop or complete study drug dosing, you will begin the last part of the study which follows your continued health condition. This is referred to as the follow-up period. The follow-up period includes the following activities:

1. **Collection of Follow-up Data.** Additional information about your health or health status may be collected in order to properly conduct the study. This information can be referred to as "necessary follow-up data". Collecting necessary follow-up data is important for this study because without it, it may be difficult to assess the safety or effectiveness of the study drug being studied or whether or not other study objectives have been met.
2. **Follow-up Contact.** Study staff may attempt to contact you to request that you come in for follow-up visits or take additional tests in order to preserve the validity or integrity of the study.
3. **Use of Third Party Representatives.** If your study doctor is unable to locate you during this follow-up period, you authorize your study doctor to disclose your contact information (e.g., your name, last known address or other relevant information) to a third-

party representative for the sole purpose of updating the study doctor and his/her study staff with your current contact information or health status. The representative(s) may be hired directly by the study sponsor. The representative(s) and the study sponsor will not contact you or your family members. The representative(s) will share your information only with the study doctor and study staff to help them complete the follow-up portion of the study.

If at any time you would like to end your participation in any of the study follow-up activities listed above, please notify your study doctor in writing and list the specific follow-up activity(ies) that you wish study staff not to perform. Even if you completely end your participation in the study, all study data that has already been collected will continue to be used and processed to maintain the integrity of the research.

Use of Your Blood Samples in this Study

Like key-coded data, these samples will be labeled with a unique code instead of your name. These samples and any information created from using these samples will be treated as key-coded data and will be used and shared only as key-coded data may be used and shared as described above in this consent.

Study-related Injuries: Treatment and Costs

If you are injured during your participation in this study, you should contact the study doctor as soon as possible in person or at the telephone number listed on page one of this consent form. Medical care may be obtained in the same way you would ordinarily obtain other medical treatment.

If you suffer a **study-related injury**, the reasonable costs of necessary medical treatment of the injury will be reimbursed to the extent these costs are not covered by your insurance or other third party coverage. A **study-related injury** is a physical injury that is directly caused by the study drug administered as described in the study protocol.

A **Study-related injury** does not include injuries directly caused by any of the following:

- The natural course of your underlying disease or medical condition
- Not following the instructions provided in this consent form or by study staff

There are no plans to provide any other payments or other forms of compensation for a study-related injury (for example, for lost wages or discomfort). You do not give up any legal rights by signing this consent form.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

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.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, 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: Pro00027493.

VOLUNTARY PARTICIPATION

Entering a research study is voluntary. Anyone who is asked to be in a research study may say no. No one has to become a research subject. If you start a research study, you may stop at any time without penalty or loss of benefit to you. You do not need to give a reason. No doctor can discriminate against you or treat you differently if you choose not to be in a research study or later decide to stop your participation. Your medical care will not be affected by your decision, nor will your ability to participate in future studies. If you stop, it is in your best interest to tell the study staff and follow any instructions that they may give you.

COMPENSATION

You will be financially compensated for your time and travel costs related to your participation in this study. You may receive up to $410 depending on how many study visits you complete. You will be compensated in the following way:

For long visits (Visits 1, 2, 4, 6, 8 and 10) $45

For short visits (Visits 3, 5, 7 and 9) $35

If you do not complete the study, you will be paid a pro-rated amount as stated above

If you are required to return for follow up visits because you develop antibodies to LI003 you will receive $45 for each visit.

You will be personally responsible for paying taxes on any compensation that you receive from your study participation according to the IRS (Internal Revenue Service) guidelines. The study doctor is required to send to you a 1099-form and report to the IRS any compensation that you receive that totals $600.00 or more for the calendar year. If you change your mailing address after your participation in the study, it is your responsibility to inform study doctor of your new mailing address in order to ensure that you receive your 1099 for your year-end tax reporting.

WITHDRAWAL

The sponsor and/or the study doctor may stop the research or stop your participation in it at any time. This may be done for many reasons (for example, if you need additional medicine, if you do not follow the study plan, if you experience a study-related injury, or for administrative reasons) and does not require your agreement.

If you withdraw or are withdrawn from the study after having taken the study drug, you will be asked to come back to the research center for a follow-up visit, which will be done for your safety. At this visit, you will have discharge procedures performed and blood tests to ensure that there are no changes to your current health status. You will be asked about any changes in your healthy or in the medications you are taking.

COSTS OF PARTICIPATING IN THE STUDY

Routine costs associated with conduct of the study will be paid by the study doctor through a grant from LIB Therapeutics, LLC. There will be no charge to you for study clinic visits, tests, study drug, or supplies related to the study.

YOUR ROLE IN THE STUDY

Your responsibilities as a study participant include the following:

- To follow the instructions you are given
- To come to the study clinic for all visits with the study doctor
- To provide truthful information about your medical history and current conditions
- To inform the study doctor or study staff if you have been in a research study in the last 30 days or are in another research study now
- To tell the study doctor or study staff about any problems you have during the study or if you have a new address or phone number
- To tell the study doctor or study staff about any prescription, over-the-counter, or herbal supplements you are taking or have taken recently
- To tell the study doctor or study staff if you want to stop being in the study at any time

FINANCIAL DISCLOSURE

If a commercial product is developed from the research performed in the Study, LIB Therapeutics, LLC will own all rights to the product. By participating in the study, you do not acquire any rights in such a product.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist.

STATEMENT OF CONSENT

I have read this form and its contents were explained. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I have been told that 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. Nothing in this form is intended to change applicable laws.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

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

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the patient. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. The subject signing this form has been given enough time and an adequate place to read and review this form. There has been an opportunity to ask questions and receive answers regarding the nature, risks, and benefits of participation in this research study. The subject appears to understand the nature and purpose of the study and the demands required of participation.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date

I attest that I or my representative discussed this study with the subject named above.

_____

Signature of Principal Investigator or Sub-Investigator

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

The United States government has issued a privacy rule to protect the privacy rights of patients and subjects in research studies. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be collected, used, and disclosed (shared).

The health information that will be obtained from you for use in the study includes:

- information obtained from your medical history, physical examinations, or other procedures to determine your eligibility for the study
- information that is created or collected from you during your participation in the study, including the results of various tests and procedures.

The above information may identify you by name, address, telephone number, photograph, social security number, health plan number, date of birth, dates relating to various tests and procedures, or other identifying information.

HOW YOUR INFORMATION WILL BE USED OR DISCLOSED

By signing this authorization, you permit the study doctor to use your personal health information to carry out and report the results of this study. The study doctor will provide your personal health information to LIB Therapeutics, LLC, the sponsor of the study, and to certain agents and representatives working on behalf of. LIB Therapeutics, LLC

By signing this authorization, you also authorize the study doctor to provide your health information to Advarra, and to the Food and Drug Administration (FDA) and other regulatory authorities in the U.S. or other countries for the purpose of assuring the quality of the study conduct, the quality of the data, or for purposes otherwise required by law.

Once your personal health information is provided to LIB Therapeutics, LLC and its agents, to Advarra IRB, or to the FDA or other regulatory authorities, your personal health information may no longer be protected by federal privacy regulations, and there is a potential that your personal health information will be passed on to others. The laws of your state may provide further protection.

ACCESS TO YOUR INFORMATION

You have the right to see and receive a copy of your records related to the study for as long as the study doctor has this information. However, while the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the study is completed.

HOW TO REVOKE YOUR AUTHORIZATION

You may cancel this authorization at any time by sending a written notice to the study doctor, whose contact information appears on page 1 of this informed consent form. If you cancel this authorization and withdraw from the study, the study doctor will stop collecting your personal health information in connection with this study unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. In addition, the study doctor will stop using and providing your personal health information, except to the extent that it has already been used. For instance, the study doctor may need to use or provide personal health information obtained before you canceled your authorization in order to preserve the scientific integrity of the study. Personal health information sent to LIB Therapeutics, LLC and its Agents prior to your cancelation may still be used by LIB Therapeutics, LLC and its agents.

If you withdraw from the study, but do not withdraw your Authorization, new personal health information may be collected until this study ends.

EXPIRATION

Your authorization for the use and disclosure of your personal health information has no expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years.

IMPORTANT NOTICE

If you do not sign this authorization or if you cancel this authorization, you will not be allowed to participate, or to continue participation, in the study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor, LIB Therapeutics, LLC, Inc. and its agents and representatives, Advarra, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

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

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the patient. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

I attest that the subject named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Obtaining Authorization

_____ _____

Signature of Person Obtaining Authorization Date