# INFORMED CONSENT DOCUMENT AGREEMENT TO BE IN A RESEARCH STUDY

**Sponsor / Study Title: <Sponsor> / <full title>**

**Protocol Number: XXXXXXXXX**

**Principal Investigator: (Study Doctor)**

**Firstname Lastname**

**Telephone: XXX-XXX-XXXX**

**Address: Address Line 1**

**Address Line 2**

**Address Line 3**

**KEY INFORMATION**

1. This is a research study and your participation is voluntary.
2. The purpose of this research study is to investigate drug levels in the blood after taking a single dose of the study drug, XXX-123, and to look at the safety and tolerability (the body’s ability to handle) of XXX-123 in healthy adults. This study will also look at the drug levels in the blood and safety and tolerability of multiple doses of XXX-123 in adults with <disease>. This study has 2 parts. If you participate in Part 1, the study should take about XX weeks of your time and you will be given a single subcutaneous (injection under the skin) dose of XXX-123 or placebo (contains no active ingredient) on Day 1. If you participate in Part 2, the study should take about XX weeks of your time and you will be given a single subcutaneous dose of XXX-123 or placebo once a week for X weeks.
3. This study drug is intended to treat patients with <disease> (<brief lay description of disease>).
4. The study drug is “investigational”. This means that it has not been approved by the United States Food and Drug Administration (FDA).
5. This is a first in human study. This means the study drug has never been given to humans before. The list of known risks / discomforts is listed later in this informed consent.
6. There will be up to XX subjects total in this study, including any replacement subjects.
7. You will get no medical benefit from this study. If you qualify for this research study, your participation may help others.

# INTRODUCTION

You are deciding if you would like to volunteer for a medical research study. You must read, sign, and date this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign and date this form if you have any questions that have not been answered.

<CRO Name> is being paid by the Sponsor (the company paying for this study) to conduct this research study.

You must be honest with the study doctor about your health history or you may harm yourself by participating in this study.

# THIS IS THE FIRST STUDY IN WHICH THE STUDY DRUG IS BEING GIVEN TO HUMANS. PURPOSE OF THE STUDY

This study drug is an investigational drug intended to treat patients with <disease> (<brief lay description of disease>). The study drug is "investigational", which means the study drug being tested is not approved by the United States Food and Drug Administration (FDA). The purpose of this study is to investigate study drug levels in the blood after taking a single dose of the study drug, XXX-123, and to look at the safety and tolerability (the body’s ability to handle) of XXX-123 in healthy adults. XXX-123 is a <description of study drug> (<brief lay explanation>). This study will also look at the study drug levels in the blood and safety and tolerability of multiple doses of XXX-123 in adults with <disease>.

In this document, you may see the terms “study drug”, “study treatment”, and “study treatment period”; these are terms used in research studies as mentioned above. This does not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

Subjects will receive a single dose (Part 1) or multiple doses (Part 2) of one of the doses of the study drug or placebo below. When assigned to a group, you will receive either XXX-123 or matching placebo (placebo looks like the investigational drug but has no active ingredients).

This is a dose escalation study. This means that in Part 1, groups of X subjects will be given a single dose of either the study drug or placebo. The first group will receive the lowest dose, and later groups will be given higher and higher dose levels until a safe limit is found.

This is a double-blind study, which means that neither you nor the study doctor will know whether you are getting the study drug or placebo. The study staff can get this information if needed. The study drug you receive will be assigned by chance, like the flip of a coin.

The design of the study is as follows: Part 1:

Groups X through X: A single injection dose of XXX-123 or placebo will be given subcutaneously (under the skin) in the abdomen (belly). The starting dose will begin at X mg. This is XXXX-fold lower than the highest dose tested in animals. Depending on the dose you receive, up to 4 (four) injections may be given at a time to receive a full dose. Data from the subjects will be reviewed after Day X and a decision will be made if the study will proceed to the next dose level. The dose level will not be known until that time. It is possible that a dose level may be repeated, or the dose reduced.

For Group 1 only, the first X subjects (a sentinel or first observed group) will receive XXX-123 or placebo on Day 1. The rest of Group 1 (the remaining X subjects) will receive their assigned dose after the safety information of the sentinel group is reviewed by the researchers.

Part 2:

A single injection dose of XXX-123 or placebo will be given subcutaneously (under the skin) to the abdomen (belly) once a week for X weeks in a row. The dose given in Part 2 will be a dose that was safe after a single dose in Part 1.

# HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

Part 1:

If you are in Part 1, the study will last for the following number of weeks:

* Groups X – X: About XX weeks, including the screening period. There will be up to X consecutive overnight stays at the facility, and X follow-up visits (to Day XX).
* Groups X – X: About XX weeks, including the screening period. There will be up to X consecutive overnight stays at the facility and X follow-up visits (to Day XX).

About XX healthy men and women, ages XX through XX, are expected to be in Part 1 of this study.

Part 2:

If you are in Part 2, the study will last about XX weeks, including the screening period, and involve 2 in- patient periods. The first in- patient period involves up to X consecutive overnight stays and X out-patient visits. The second in- patient period involves up to X consecutive overnight stays and X follow-up visits.

About XX men and women with <disease>, ages XX through XX, are expected to be in Part 2 of this study.

# TO BE IN THIS STUDY

You cannot be in this study if you meet any of the following criteria:

* Have a history of <disease or condition>.
* Have blood pressure greater than 155 mmHg systolic or greater than 95 mmHg diastolic.
* Have known heart disease or clinically significant abnormalities identified in the 12-lead ECG at Screening.
* Are a female who is pregnant or lactating at screening.
* Have a history of alcohol or drug/chemical abuse within X years before the screening visit.
* Have alcohol use of greater than XX units per week for males and greater than XX units per week for females. One unit of alcohol equals 12 oz (360 mL) beer, 1.5 oz (45 mL) liquor, or 5 oz (150 mL) wine.
* Have a positive urine result for alcohol or drug use. You must abstain from alcohol from 48 hours before Check-in until Check-out from the unit. You may be observed during urine sample collection.
* Have previously received XXX-123 or any other <therapy type> that works the same way as XXX-123.
* Are in another research study or if you have been in any other research study in which you received study drug within 30 days (or more depending on the specific study drug) before the first dose of study drug in this study.
* Have a history of significant hypersensitivity, intolerance, or allergy to more than one class of drugs.
* Have liver function tests (groups of blood tests that show how your liver is working) that are high.
* Have a positive test for human immunodeficiency virus (HIV) or hepatitis.
* Have previously completed or were withdrawn from this study. If you were an alternate for a previous group, were not assigned to a treatment, and did not receive study drug, you are eligible to participate in another group.
* Have an allergy to lidocaine or have used anticoagulants (blood thinners) in clinically significant amounts.

Subject Responsibilities:

While participating in this research study, you will need to follow these conditions:

* Be able to follow the study directions and procedures.
* Tell the study staff about any side effects or problems.
* Ask questions as you think of them.
* Tell the study doctor or the study staff if you change your mind about staying in the study.
* Do not donate blood from X weeks (XX weeks for double red cell donation) before screening until XX days after the final follow-up visit.
* If you are male, do not donate sperm from check-in until X months after the last dose of study drug.
* Do not eat or drink caffeine- or xanthine-containing products (for example, coffee, tea, cola drinks, and chocolate) from XX hours before check-in until check-out from the clinic.
* Do not use tobacco or nicotine-containing products (including nicotine patches) while in the clinic.
* Do not use marijuana, tetrahydrocannabinol (THC), cannabidiol (CBD), or other cannabinoids from XX days before screening through the end of participation in the study.
* You must agree to have your blood drawn for genetic testing.
* Part 1 Groups:
  + Do not use any prescription or nonprescription medications or nutritional products including vitamins (except ongoing multivitamin supplement), minerals, and phytotherapeutic (natural plant derived medicines), herbal, or plant-derived preparations from screening until the end of the study.
  + Avoid strenuous activity from XX hours before check-in and each follow-up visit.
* Part 2 Group:
  + If you are on medications for <disease>, your dose must be stable for at least XX days before screening and may not be changed from screening until the end of study without approval by the study doctor.
  + Avoid strenuous activity from XX hours before check-in and each follow-up visit. You can continue your usual activity or exercise regimen, but you cannot increase intensity of your activity or exercise regimen during the study.

This study involves testing an investigational drug developed by the Sponsor. We ask subjects to keep information as confidential as possible. This would include not sharing details of the study, including requirements for participation, information received on the risks and benefits of dosing with this study drug, and symptoms or reactions to study drug while enrolled in the study, with persons other than the clinic staff, your family, and your healthcare provider. This would also include not disclosing such information on social media sites or webpages.

# WHAT WILL HAPPEN DURING THE STUDY

**Screening**

Before the study starts, you will be asked to sign and date this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The study doctor will do some tests to find out if you can be in the study. These tests include:

* Physical exam, including vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry [the amount of oxygen in your blood]), height and weight.
* An electrocardiogram (ECG) will be taken; this is a recording of the electrical activity of your heart.
* Lab tests (blood and urine); you must fast (nothing to eat or drink, except water) for at least XX hours before these tests.
* Blood test for HIV and hepatitis B and C.
* Urine test for drugs of abuse (illegal and/or prescription), including alcohol.
* Blood pregnancy tests for female subjects.
* Follicle stimulating hormone (FSH) test for female subjects claiming postmenopausal status.
* You will be asked whether you’ve had the COVID-19 vaccine, which version you’ve had, and how many doses.

The Screening Visit may take up to X hours and XX minutes of your time.

If you qualify for the study, you will return to the clinic within XX days for the Study Period. If you are more than 1 hour late to your study check-in, you may be placed in alternate/backup status.

**Study Procedures Check-in/Day X**

The following will be done at Check-in/Day X.

* You will be asked questions to be sure that you still qualify for this study.
* You will be asked about any changes in your health or over-the-counter or prescription medicines, vitamins or herbs you have taken since your last visit.
* If you are female, a urine pregnancy test will be performed.
* A urine sample will be taken – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position (Part 1 only).
* A physical exam will be done.
* A COVID-19 test will be done.

**Part 1**

**Single Dose**

The following will be done during the In-Patient part of the study:

* Standard meals will be given at scheduled times during your stay in the clinic.
* About X teaspoon (X mL) of blood will be taken on Day X for genetic testing.
* The study drug you receive will be assigned by chance, like the flip of a coin (Day X only).
* You will have to fast (nothing to eat or drink except water) for at least XX hours before taking study drug.
* You will be given a subcutaneous (under the skin) injection to the abdomen (belly). Your injection site will be carefully monitored. Depending on the dose you receive, up to 4 (four) injections may be given at a time in order to receive a full dose.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position at various times during your stay in the clinic.
* Triplicate (3 times) ECGs will be taken at various times during your stay in the clinic.
* Weight will be measured at various times during your stay in the clinic.
* Blood will be taken to measure the level of study drug in your blood, to measure biomarkers (the effect of the study drug on your body), to measure cytokines (aid in your body’s immune response), and to measure antibodies to the study drug. Blood will be taken one time on Day X, one time before dosing, and XX times after dosing.
* Lab tests (blood and urine) will be collected on following days: <list of days>; you must fast for at least XX hours before these tests.
* A urine sample will be taken on following days: <list of days> – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription) A physical exam will be done on following days: <list of days>.
* Ongoing monitoring of any changes in your health and medication usage.
* You will be discharged from the study clinic after all procedures are completed on Day X and return for follow-up visits on Days XX, XX, XX, XX and XX.
  + If you are in groups X – X, you will also return for follow-up visits on Days XX and XX.

**Follow-Up Visits**

The following procedures will be done at the follow-up visits:

* A urine sample will be taken at each visit – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* If you are female, a urine pregnancy test will be performed on Day XX (groups X-X) or Day XX (groups X-X).
* Weight will be measured on Days XX and XX.
  + If you are in groups X-X, weight will also be measured on Day XX.
* Blood will be taken to measure the level of study drug in your blood, to measure biomarkers (similar to lab tests), and to measure antibodies to the study drug. Blood will be taken one time at each visit.
* Lab tests (blood and urine) will be collected on Days XX and XX.
  + If you are in groups X-X, lab tests will also be collected on Day XX.
  + You must fast for at least XX hours before these tests
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position on Days XX, XX, and XX. If you are in groups X-X, vital signs will also be measured on Day XX.
* An ECG will be taken on Day XX. If you are in groups X-X, an ECG will also be taken on Day XX.
* A physical exam will be done on Day XX (groups X-X) or Day XX (groups X-X).
* Ongoing monitoring of any changes in your health and medication usage.

**Early Discontinuation**

The following will be done if you leave the study early:

* A urine sample will be taken – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* If you are female, a urine pregnancy test will be done.
* Weight will be measured.
* Blood will be taken to measure the level of study drug in your blood and to measure antibodies to the study drug. Blood will be taken one time.
* Lab tests (blood and urine) will be collected; you must fast for at least XX hours before these tests.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position.
* An ECG will be taken.
* A physical exam will be done.

**Part 2**

**Repeat Dosing**

The following will be done during the In-Patient parts of the study when you are in the clinic from Day X to Day X and Day XX to Day XX:

* Standard meals will be given at scheduled times during each stay at the clinic.
* About X teaspoon (X mL) of blood will be taken on Day X for genetic testing.
* The study drug you receive will be assigned by chance, like the flip of a coin (Day X only).
* You will have to fast (nothing to eat or drink except water) for at least XX hours before taking study drug Day X and Day XX.
* You will be given a subcutaneous (under the skin) injection to the abdomen (belly). Your injection site will be carefully monitored. Depending on the dose you receive, up to 4 (four) injections may be given at a time in order to receive a full dose.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position at various times during each stay at the clinic.
* Triplicate (3 times) ECGs will be taken at various times during each stay at the clinic.
* Weight will be measured at various times during each stay at the clinic.
* Blood will be taken to measure the level of study drug in your blood, to measure biomarkers (similar to lab tests), and to measure antibodies to the study drug. Blood will be taken one time on Day X; one time before dosing and X times after dosing on Days X-X; one time on Day XX; and one time before dosing and X times after dosing on Days XX-XX.
* Urine will be collected throughout each in-patient period.
* A physical exam will be done at various times during each stay at the clinic.
* Lab tests (blood and urine) will be collected on Day X and Days X, XX, and XX; you must fast for at least XX hours before these tests.
* A urine sample will be taken on Day XX – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* If you are female, a urine pregnancy test will be done on Day XX.
* Ongoing monitoring of any changes in your health and medication usage.
* You will be discharged from the study clinic after all procedures are completed on Day X and return for out-patient visits on Days X and XX. After your second stay at the clinic (Days XX – XX), you will be discharged after all procedures are completed on Day XX and return for follow-up visits on Days XX, XX, XX, XX, and XX.

**Study Treatment Period – Out-Patient Visits (Days X and XX)**

The following procedures will be done at the out-patient visits:

* You will have to fast (nothing to eat or drink except water) for at least XX hours before taking study drug on Days X and XX.
* You will be given a subcutaneous (under the skin) injection to the abdomen (belly) on Days X and XX. Your injection site will be carefully monitored. Depending on the dose you receive, up to 4 (four) injections may be given at a time in order to receive a full dose.
* A urine sample will be taken on Days X and XX - the urine tests will include finding out if you have used any alcohol, tobacco, or drugs of abuse (illegal and prescription).
* Weight will be measured on Day XX.
* Blood will be taken to measure the level of study drug in your blood and to measure antibodies to the study drug. Blood will be taken one time at each visit on Days X and XX.
* Lab tests (blood and urine) will be collected on Days X and XX; you must fast for at least XX hours before these tests.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position on Days X and XX.
* Ongoing monitoring of any changes in your health and medication usage.

**Follow-Up Period (Days XX, XX, XX, XX, XX, XX, XX, XX)**

The following procedures will be done at the follow-up visits:

* A urine sample will be taken on Days XX, XX, XX, and XX - the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* Weight will be measured on Days XX, XX, and XX.
* Blood will be taken to measure the level of study drug in your blood, to measure biomarkers (similar to lab tests), and to measure antibodies to the study drug. Blood will be taken one time at each visit on Days XX, XX, XX, XX, XX, XX, and XX.
* Lab tests (blood and urine) will be collected on Days XX, XX, XX, and XX; you must fast for at least XX hours before these tests.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position on Days XX, XX, XX, XX, XX, XX, XX, and XX.
* An ECG will be taken on Day XX.
* Triplicate ECGs will be done on Day XX.
* A physical exam will be done on Day XX.
* Ongoing monitoring of any changes in your health and medication usage.

**Early Discontinuation**

The following will be done if you leave the study early:

* A urine sample will be taken – the urine tests will include finding out if you have used any alcohol or drugs of abuse (illegal and prescription).
* If you are female, a urine pregnancy test will be done.
* Weight will be measured.
* Blood will be taken to measure the level of study drug in your blood, to measure biomarkers (similar to lab tests), and to measure antibodies to the study drug. Blood will be taken one time.
* Lab tests (blood and urine) will be collected; you must fast for at least XX hours before these tests.
* Vital signs (blood pressure, temperature, heart and breathing rates and pulse oximetry) will be measured in a laying down position.
* An ECG will be taken.
* A physical exam will be done.

Blood Samples:

Blood samples will be taken by single needle-sticks or by a tube that is left in your arm. You cannot choose how the blood is taken.

Part 1, Groups X-X:

There will be about XX blood draws. The total amount of blood drawn will be about XX mL, or about X cup.

Part 1, Groups X-X:

There will be about XX blood draws. The total amount of blood drawn will be about XX mL, or a little less than X cup.

Part 2:

There will be about XX blood draws. The total amount of blood drawn will be about XX mL, or about X cup.

For comparison, the standard blood donation is about 480 mL (2 cups). Additional blood may be drawn and additional tests performed for your safety.

# HIV, HEPATITIS, AND COVID-19 TESTING

You must be tested for coronavirus. Coronavirus is the virus that causes the disease COVID-19. If you have a positive coronavirus test at check-in (Day X), you cannot be in the study.

You must have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes AIDS. If you have a positive HIV or hepatitis test you cannot be in the study.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

We are required to report positive HIV test results and COVID-19 test results to the <local health authority>. We may also be required to report positive hepatitis test results to the <local health authority>. Positive HIV and all COVID-19 test results may be required to be reported to the <state health authority>. If you have any questions about what information is required to be reported, please ask the study doctor or study staff.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

Additionally, in the unlikely event that a <CRO Name> employee has been exposed to your blood or other body fluid either through a needle stick injury, splash incident or contact with broken skin (for example, cut, bite), additional samples may be collected to determine and confirm whether or not you have a certain infection. Your de-identified results will be released to the injured employee, and to the health care provider evaluating and treating that employee, to aid the injured employee and the medical provider make decisions regarding his/her medical treatment and follow-up care as a result of this on-the- job exposure.

**COVID-19 Testing**

COVID-19 testing will be completed as a safety precaution for you and our study staff. You will receive a PCR, or nasopharyngeal swab test, which will indicate if you are currently fighting the virus and are contagious. It is possible that you may not experience any COVID-19 symptoms but still test positive and have the ability to infect others with the virus. These tests are meant to detect that.

PCR Test (nasopharyngeal swab collection)

The SARS-CoV-2 (COVID-19), Real-Time RT-PCR test is test that aids in the detection of COVID-19. The RT-PCR test starts with a nasal swab collection, which is designed to capture virus genetic material, and this testing method is both specific and sensitive. This means that people who test positive are considered to have the illness and are contagious. If receiving this test, you will have a trained individual collect a nasopharyngeal swab (upper part of throat, behind the nose – both nostrils) sample from you.

You may not be experiencing symptoms, but it is possible to be infected with this virus, so this test is meant to detect that.

# PHARMACOGENETICS

As part of this study, we are asking you to provide a blood sample (about X teaspoons) for genetic research. Cells in your blood have DNA that include the genes that provide the instructions for making our bodies, such as how tall you are, the color of your eyes, whether you are male or female, and what diseases you might get. Your DNA can also tell us where in the world your ancestors came from.

Researchers would like to study your DNA to help them understand why medicines like the one being used in this study work in some people and not in others. The researchers may also look at your DNA to help them understand what is causing <disease>. This information may help researchers make better medicines in the future.

Your DNA sample will be labeled with a code and not with your name or birthday to protect your identity and will be stored in a secure location until it is all used up or XX years, whichever is sooner. You can ask for your DNA sample to be destroyed at any time and your sample will not be used for any new research, but any research data that has already been generated will not be destroyed.

You have the right to withdraw your consent to participate in genetic testing at any time by notifying the study doctor in writing and requesting that your sample be destroyed. Your blood sample will be destroyed, but the Sponsor will keep and use any research information it has already obtained. You must provide your request to withdraw from participation in genetic testing to the study doctor in writing at the address listed below:

<CRO Name>

ATTN: <Firstname Lastname>

Address Line 1

Address Line 2

Address Line 3

The results of this genetic research will not be returned to you or provided to your study doctor; it will be kept in a secure location to protect your privacy. We will not sell your sample or data, but we may work with other companies to do research on your sample and data.

Sometimes the research involving your sample may lead to new inventions or medicines that have value if they are sold, you would not get any money from these inventions.

Risks:

* Physical risks: you may have a sore arm from where the blood sample is taken.
* Nonphysical risks: Your sample and data will be kept in a secure location, and every effort will be made to protect any information about you. While it is unlikely, it is possible that information about your DNA could be made known.

# FUTURE TESTING OF BLOOD SAMPLE

The sponsor would like to keep the blood samples collected in the course of the study for future research to continue analyzing it for genes involved in the safety, pharmacokinetics (what the body does to a drug) and pharmacodynamics (how a medicine acts in the body) of the study drug, XXX-123. This information may be useful in increasing the knowledge of differences among individuals in the way they metabolize the investigational product as well as helping in the development of new drugs or improvement of existing drugs. You will not have any right to any such products or inventions or be entitled to any financial benefits from any such products. The information may be published or used for regulatory filings, but your identity will never be disclosed.

The sample will be retained in a secure location until the deoxyribonucleic acid (DNA - the material that determines your unique characteristics such as eye and hair color, and also influences the way your body responds to certain drugs and hereditary disease factors) has been exhausted, until the sponsor instructs the genotyping contractor to destroy the sample in accordance with laboratory procedures, or for XX years. During this time, the DNA sample will not be immortalized or sold to anyone.

The result of the future testing done by the sponsor will not be given to you or the study doctor.

You have the right to withdraw your consent to participate in future testing at any time by notifying the study doctor in writing and requesting that your sample be destroyed. Your blood sample will be destroyed, but the Sponsor will keep and use any research information it has already obtained. You must provide your request to withdraw from participation in future testing to the study doctor in writing at the address listed below:

<CRO Name>

ATTN: <Firstname Lastname>

Address Line 1

Address Line 2

Address Line 3

In order to ensure confidentiality, your sample will be identified only by a barcode identifier. This barcode will be linked to your study identification number and ethnic background.

# POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

Because this drug is investigational, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study. The study staff will continue to follow up if you have side effects that are still present at the end of the study.

XXX-123 has not been given to humans, so no information about side effects are available.

In animal studies, there were no side effects observed at doses approximately XX-fold larger than the highest dose you could receive in this study.

Other drugs similar to XXX-123 have been studied in humans. The most common side effects seen in people given similar drugs include:

* <side effect>
* <side effect>
* <side effect>
* <side effect>

Although the study drug, XXX-123, has not been shown to get into the brain, you will be closely monitored for the following side effects that have been seen when taking a similar type of drug that do get into the brain:

* <side effect>
* <side effect>
* <side effect>
* <side effect>

You may form antibodies to the study drug. An antibody is a type of protein that helps protect the body against attack by bacteria and viruses. There is also a chance that if you have these antibodies, this study drug or similar drugs will not work for you in the future.

All drugs may cause allergic reactions in some people. Below is a list of symptoms of an allergic reaction:

* Swelling of the face, lips, throat, and other areas of the skin
* Difficulty swallowing or breathing
* Raised, red areas on your skin
* Skin rash, itching, flaking, or peeling

If you have a side effect of the study drug, such as a skin rash or other visible injury, it might be useful to take a digital picture of the affected area to send to the sponsor. By signing and dating this consent, you authorize the study doctor or study staff to take such a picture and provide it to the sponsor. Every effort will be made to protect your identity if a photograph is necessary.

# ADDITIONAL RISKS OR DISCOMFORTS

Blood Samples (taken by single needle-sticks or by a tube that is left in your arm):

There may be side effects of having blood drawn such as:

* Fainting
* Redness
* Pain
* Bruising
* Bleeding
* Infection
* Blood clots, which may cause inflammation, swelling and pain
* Nerve damage
* Scarring

If you feel faint tell the study staff right away. Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Fasting

Fasting could cause dizziness, headaches, stomach discomfort or fainting.

Risks of using Lidocaine:

A rare but possible side effect of lidocaine is an extreme allergic reaction. These symptoms may include:

* Severe shortness of breath
* Swelling of the throat
* Redness, swelling, and tenderness of the skin
* Skin rash

Risks of Subcutaneous (SC) Injection:

* Infection
* Pain
* Redness
* Bruising
* Local swelling
* Warmth or drainage

**Non-Physical Risks Associated with the Planned Genetic Analysis and Future Research of Biomarker Samples:**

Loss of confidentiality is the primary risk of testing, collecting, and storing tissue/blood samples. It may be possible for DNA to be extracted (through various testing methods) from the donated tissues/blood, which would allow knowledge about you to be gained that you may not want known. Your test results are confidential. The Sponsor will make every effort to protect any information about you, generated from testing and analysis of your samples, from anyone other than the people or companies you read about in this form. We believe that the benefits of learning more about human genetic variation and how it relates to health and disease outweigh the current and potential future risks, but this is something that you must judge for yourself.

There are also current limited protections afforded to you by a U.S. Federal law, the Genetic Information Non-discrimination Act (GINA), which protects you from discrimination based on your genetic information in both health insurances and employment. All health insurance companies and group health plans provided by employers with 15 or more employees must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long term-care insurance, nor does it prohibit discrimination based on a genetic disease or disorder that you already know about.

# BIRTH CONTROL AND DANGERS OF PREGNANCY AND BREASTFEEDING

You must be of non-childbearing potential (not able to have children) to be in this study. This includes:

* Premenopausal with one of the following:
  + Documented hysterectomy (removal of the uterus)
  + Documented bilateral salpingectomy (removal of both fallopian tubes)
  + Documented bilateral oophorectomy (removal of both ovaries)
* Postmenopausal (no menstrual periods for 12 months without an alternative medical cause). Subjects who are postmenopausal will have a follicle-stimulating hormone (FSH) test performed at screening to confirm postmenopausal status.
* Permanent infertility (not being able to become pregnant) due to an alternative medical cause (for example, mullerian agenesis – congenital malformation resulting in a missing uterus)

If you are a female on hormone replacement therapy and whose menopausal status is unable to be confirmed, you will be required to use non-estrogen hormonal highly effective contraception methods during the study and for X months after the last dose, if you continue hormone replacement therapy.

Otherwise, you must discontinue your hormone replacement therapy to allow confirmation of postmenopausal status before the study begins.

If you are a man (even if you have a history of vasectomy), you must use birth control if you choose to have sex with women while in this study. You must also not donate sperm during the study and for at least X months after the last dose of study drug*.*

You will be required to use a male condom with spermicide in addition to a second method of acceptable contraception from study check-in until X months after the final follow-up visit.

Acceptable second methods of birth control for female partners include:

* Hormonal injection
* Combined oral contraceptive pill or progestin/progestogen-only pill
* Combined hormonal patch
* Combined hormonal vaginal ring
* Bilateral tubal ligation (tubes tied)
* Hormonal implant
* Hormonal or non-hormonal intrauterine device (IUD)
* Over-the-counter sponge with spermicide
* Cervical cap with spermicide
* Diaphragm with spermicide

Sexual intercourse with a female partner who is pregnant or breastfeeding should be avoided unless condoms are used from the time of the first dose until X months after the final follow-up visit.

Even if you use birth control during the study, there is a chance you or your partner could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug may involve unforeseeable risks to the unborn baby. A pregnancy test is not always correct, especially in the early stages of pregnancy.

If you become pregnant during the study or within X months after the last dose of the study drug, you should inform the study doctor. If you are still receiving the study drug when you become pregnant, you will have to stop taking the study drug and will be removed from the study. If this happens, you will be provided with a separate Consent Form to sign in order to agree to follow up on the pregnancy, its outcome and the health of the baby after delivery.

If your female partner becomes pregnant during the study or within 6 months after the last dose of the study drug, you should inform the study doctor. She will be provided with a separate Consent Form to sign in order to agree to follow up on the pregnancy, its outcome and the health of the baby after delivery.

# POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from this study, other than the benefit of free medical tests. You may receive a chance to be in a research study that may help others.

# ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

# CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

* The study doctor
* Sponsor company or research institution [including monitor(s) and auditor(s)]
* The United States Food and Drug Administration (FDA)
* Other state or federal regulatory agencies
* <IRB Company> IRB

After the research, identifiers might be removed and your de-identified information or bio-specimens may be used for future research without additional informed consent.

The sponsor may share the study data with third parties for research and the development of drugs and diagnostics. The study data may be submitted to regulatory authorities for purposes of applying for approval of the study drugs or other drug candidates and diagnostics. It may also be used to better understand kidney disease and may be shared with third parties for presentation and publication purposes. However, your identity will not be disclosed.

A description of this clinical study will be available on [www.ClinicalTrials.gov.](http://www.clinicaltrials.gov/) This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you withdraw or are withdrawn from the study, no new information about you will be collected; however, the data collected up to the point of withdrawal can continue to be used.

The Institutional Review Board (IRB), <IRB Company>, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

# IN CASE OF STUDY RELATED INJURY

If you are injured from 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 physical injury that is directly caused by the study drug given as described in the study protocol or by a properly performed medical procedure required by the protocol, the reasonable costs of necessary medical treatment of the injury will be reimbursed by the Sponsor to the extent these costs are not covered by your insurance or other third-party coverage.

Expenses for a study-related injury are offered provided that:

* The injury or condition is not the result of the natural course of any underlying disease or medical condition
* The instructions provided in this consent form or given by the study staff have been followed No payment or other forms of compensation are offered (for example, lost wages or discomfort).

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

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.

# LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

# 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 study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

* By mail:

Address Line 1

Address Line 2

Address Line 3

* or call **toll free**: XXX-XXX-XXXX
* or by **email**: <email address>

Please reference the following number when contacting the Study Subject Adviser: Pro00050709.

<IRB Company> has approved the information in this consent form and has given approval for the study doctor to do the study. This does not mean <IRB Company> has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

# PAYMENT FOR BEING IN THE STUDY

If you are in Part 1, Groups X-X, you may receive up to $XXXX.00 for being in this study. This money covers the costs for time spent at the clinic and is to help cover travel expenses to and from <CRO Name>. You will be paid per completed visit as follows:

| **In-Residence Period** | **Visit** | **Compensation (amount)** |
| --- | --- | --- |
| Check-in / Day -2 | $XXX.00 |
| Day -1 | $XXX.00 |
| Day 1 | $XXX.00 |
| Day 2 | $XXX.00 |
| Day 3 | $XXX.00 |
| Day 4 | $XXX.00 |
| Day 5 | $XXX.00 |
| Day 6 | $XXX.00 |
| Day 7 | $XXX.00 |
| Day 8 | $XXX.00 |
| **Follow-Up Period** | Day 11 Follow-Up Visit | $XXX.00 |
| Day 15 Follow-Up Visit | $XXX.00 |
| Day 22 Follow-Up Visit | $XXX.00 |
| Day 29 Follow-Up Visit | $XXX.00 |
| Day 43 Follow-Up Visit | $XXX.00 |
|  | Total | $XXXX.00 |

If you are in Part 1, Groups X-X, you may receive up to $XXXX.00 for being in this study. This money covers the costs for time spent at the clinic and is to help cover travel expenses to and from <CRO Name>. You will be paid per completed visit as follows:

| **In-Residence Period** | **Visit** | **Compensation (amount)** |
| --- | --- | --- |
| Check-in / Day -2 | $XXX.00 |
| Day -1 | $XXX.00 |
| Day 1 | $XXX.00 |
| Day 2 | $XXX.00 |
| Day 3 | $XXX.00 |
| Day 4 | $XXX.00 |
| Day 5 | $XXX.00 |
| Day 6 | $XXX.00 |
| Day 7 | $XXX.00 |
| Day 8 | $XXX.00 |
| **Follow-Up Period** | Day 11 Follow-Up Visit | $XXX.00 |
| Day 15 Follow-Up Visit | $XXX.00 |
| Day 22 Follow-Up Visit | $XXX.00 |
| Day 29 Follow-Up Visit | $XXX.00 |
| Day 43 Follow-Up Visit | $XXX.00 |
|  | Total | $XXXX.00 |

If you are in Part 2, you may receive up to $XXXX.00 for being in this study. This money covers the costs for time spent at the clinic and is to help cover travel expenses to and from <CRO Name>.

You will be paid per completed visit as follows:

|  | **Visit** | **Compensation (amount)** |
| --- | --- | --- |
| **In-Residence Period** | Check-in / Day -2 | $XXX.00 |
| Day -1 | $XXX.00 |
| Day 1 | $XXX.00 |
| Day 2 | $XXX.00 |
| Day 3 | $XXX.00 |
| Day 4 | $XXX.00 |
| Day 5 | $XXX.00 |
| **Out-Patient Visits** | Day 8 Out-Patient Visit | $XXX.00 |
| Day 15 Out-Patient Visit | $XXX.00 |
| **In-Residence Period** | Day 21 | $XXX.00 |
| Day 22 | $XXX.00 |
| Day 23 | $XXX.00 |
| Day 24 | $XXX.00 |
| Day 25 | $XXX.00 |
| Day 26 | $XXX.00 |
| **Follow-Up Period** | Day 29 | $XXX.00 |
| Day 32 | $XXX.00 |
| Day 36 | $XXX.00 |
| Day 43 | $XXX.00 |
| Day 50 | $XXX.00 |
| Total | $XXXX.00 |

If you choose to leave or are withdrawn from the study for any reason before finishing all visits, you will be paid for each completed visit. You will receive payment within 2 weeks after your last study visit, or if you choose to leave or are withdrawn from the study for any reason.

You will not be paid for the screening visit.

No other payment will be offered to you. You will receive your payment within two weeks of your final visit.

If you are a backup subject who has to stay the night in the clinic, you will be paid $XXX.00 per night. If you do not have to stay the night, you will be paid $XX.00.

You must follow the <CRO Name> in-patient clinic rules of conduct while you are taking part in this study. If you do not follow the rules, part of your payment (not to exceed the amount of the additional payment) may be taken away. You may not be able to take part in other studies at <CRO Name>. These rules will be reviewed with you at the screening visit and are available on the <CRO Name> website.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

# VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. All subjects are considered a back-up until told otherwise. No one can be sure they will be in a study.

The study doctor, the sponsor company, <IRB Company>, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

* If you do not follow the study doctor’s instructions
* If we find out you should not be in the study
* If the study is stopped
* If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to remain at the research site for observation or completion of additional safety procedures (such as ECGs, vital signs, safety labs, etc.). If you leave the study early or if you are taken out of the study, you will be asked to complete a final visit to have some end of study evaluations or tests performed. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

# ADDITIONAL COSTS

There is no cost to you during the study for any of the following:

* Any study test or procedure, including physical exam and blood tests
* Study drug

# NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation, we will tell you. You can then decide if you still want to be in the study.

# AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

1. Is this document in a language you understand?
2. Do you understand the information in this consent form?
3. Have you been given enough time to ask questions and talk about the study?
4. Have all of your questions been answered to your satisfaction?
5. Do you think you received enough information about the study?
6. Do you volunteer to be in this study of your own free will and without being pressured by the study doctor or study staff?
7. Do you know that you can leave the study at any time without giving a reason and without affecting your health care?
8. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities?
9. Do you know that you cannot be in another study while you are in this study?

# IF YOU ANSWERED “NO” TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,

**YOU SHOULD NOT SIGN AND DATE THIS CONSENT FORM.**

**You will be given a signed and dated copy of this consent form to keep.**

| Printed Name of Adult Study Subject |  | | |
| --- | --- | --- | --- |
| Signature of Adult Study Subject | Date | Time (24-hour clock) |  |
| Printed Name of Person Explaining Consent Form |  |  |  |
| Signature of Person Explaining Consent Form | Date | Time (24-hour clock) |  |