AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, US Department of Health and Human Services / "A Phase 1, Randomized, Double-Blind, Multi-Site, Single Dose Escalation Study to Evaluate the Safety, Pharmacokinetics, and Immunogenicity of SAR440894 vs Placebo in Healthy Adults"**
Protocol Number:	**18-0006**
Principal Investigator: (Study Doctor)	**Kristie Miller, MD**
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CONCISE SUMMARY

The purpose of this study is to find out whether an investigational drug, SAR440894, is safe, find out how it is absorbed, distributed, and excreted as well as if the study drug will cause an immune response (the way your body fights off infection).

This is the first time that SAR440894 will be given to humans.

If you sign a consent form, you will undergo screening procedures to see if you qualify. If you qualify and wish to continue, you will be asked to return to the PPD Austin CRU for a 4- night overnight stay. There will also be 7 follow-up visits which will occur after discharge. Your participation in the study will last approximately 5 months. You will have the following procedures performed at various times throughout the study: vital signs, electrocardiograms (ECGs), blood collection, urine collection, and physical exam. Randomization is assigned by chance (like the flip of a coin). You will be randomized to receive either SAR440894 or a placebo. A placebo looks like the study drug but does not contain any active study drug in it. The exact dose of SAR440894 you may receive will depend on when you enroll in this study. The

dose will increase with each group of participants until the safest and best tolerated dose is reached. SAR440894 will be administered intravenously (IV); a small tube placed in your arm). You may receive a single dose of up to 20 mg for every 1 kilogram of your body weight of SAR440894 in this study.

This is a double-blind study which means that neither you nor the study staff will know if you are taking the study drug or placebo. The study staff can get this information if needed.

There are risks to this study drug that are described in this document. Common risks in similar drugs that are generally mild include:

- Fever
- Chills
- Shivering
- Nausea
- Vomiting
- Pain
- Headache
- Dizziness
- Shortness of breath
- Tightening of airway
- Low blood pressure
- High blood pressure
- Itchy skin
- Rash
- Hives
- Swelling
- Diarrhea
- Fast heart rate
- Chest pain

In addition, SAR440894 did show a mild to moderate, temporary increase in the amount of protein and blood in the urine when given to mice.

The kidney changes were not seen when SAR440894 was given to non-human primates. There could also be additional risks which could be serious that have not yet been identified.

If you agree to take part in this study, there will be no direct medical benefit to you. If you are interested in learning more about this study, please continue reading below.

You are being asked to volunteer for this medical research study because you are a healthy individual 18-45 years of age who does not have any known health conditions. Research studies are voluntary and include only people who choose to take part. Before you decide whether or not to volunteer, you must read, understand, and sign and date this form. This form, called a consent

document, explains the study. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study. To be in this research study, you cannot already be in another medical research study at any facility or have received a drug/treatment in another medical research study within 45 days or 5 half-lives (whichever is longer) before study drug administration.

The National Institutes of Health's (NIH) Division of Microbiology and Infectious Diseases (DMID) will sponsor this study. Portions of the study doctor's and his/her research team's salaries will be paid by this funding.

WHO WILL BE MY STUDY DOCTOR ON THIS STUDY?
If you decide to participate, Kristie Miller, M.D. will be your doctor for the study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to find out whether an investigational drug is safe, find out how it is absorbed, distributed, and excreted, as well as if the study drug will cause an immune response (the way your body fights off infection). "Investigational" means the study drug is being tested for safety and effectiveness and has not been approved by the Food and Drug Administration (FDA) for use in the United States. 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, and 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 study drug or placebo. In this informed consent form, the investigational drug will be referred to as SAR440894. The study will also measure how long it takes for the body to remove the study drug from the bloodstream, as well as determine if this study drug will trigger an immune response (the way your body fights off infection).

SAR440894 is a monoclonal antibody being studied as a possible treatment for people with chikungunya virus (CHIKV). Monoclonal antibodies are proteins of the immune system made artificially to attack foreign bacteria or cells that are invading the body. CHIKV is a mosquito-transmitted virus which can cause many complications, including inflammation of the joints (arthritis) that may last for months to years. Research studies conducted on animals with CHIKV that were treated with SAR440894 show a decrease in the virus and a decrease of symptoms of infection.

This is the first time that SAR440894 will be given to humans. This study will look at the safety of SAR440894 and will look at how the amount of study drug in the blood changes over time.

NEW FINDINGS

You will be informed of any new information or any significant new findings that could relate to your willingness to participate in this study. You can then decide if you still want to continue as a participant in this study.

If the FDA or the sponsor makes changes to the study before the study starts, the study staff will try to notify you before you check-in. If changes are made after the study has started, the study staff will tell you about them as soon as they have been approved. You can use this information to decide if you want to stay in the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study is expected to enroll approximately 40 participants. This PPD Austin Clinical Research Unit (CRU) is one of several sites taking part in this study.

WILL ELECTRONIC SIGNATURE BE ACCEPTABLE?

If your local laws allow, you will review and sign the ICF electronically. After you have read and understood the contents of this ICF and if you decide to take part in the study, you will be asked to sign the ICF electronically to show your willingness to participate.

WHAT IS INVOLVED IN THE STUDY?

You will be enrolled into one of five dosing groups. Each group will receive a higher dose of study drug than the group before them. You will be randomly assigned (like the flip of a coin) to receive either SAR440894 or placebo. A placebo is an inactive substance given in the same form as the study drug. The first two participants dosed in each dosing group will have a 1 in 2 (50%) chance of receiving SAR440894 or a placebo. Of the remaining 6 participants in each dosing group, you have a 5 in 6 (83%) chance of receiving SAR440894 and a 1 in 6 (17%) chance of receiving a placebo. Neither you nor the study doctor and other members of the study staff will know if you are getting SAR440894 or placebo. However, in an emergency, the study doctor can find out.

You will receive one dose of study drug on Day 1. You will receive study drug by IV infusion through a vein in your arm over approximately 60 minutes. Intravenous infusion (IV dosing) is where the study drug solution is given through a needle into your hand or arm vein by an IV pump. An IV pump is a machine that controls how fast you receive the study drug.

The planned doses in the study are:

- Group 1 (8 participants): 0.3 mg/kg of SAR440894 or placebo
- Group 2 (8 participants): 1 mg/kg of SAR440894 or placebo
- Group 3 (8 participants): 3 mg/kg of SAR440894 or placebo
- Group 4 (8 participants): 10 mg/kg of SAR440894 or placebo
  Group 5 (8 participants): 20 mg/kg of SAR440894 or placebo

The study doctor and medical monitor will review safety data from lower doses before giving the next higher dose. There is a chance the dose could be lower than the original planned dose, however it will not be higher.

For safety reasons, the first 72 hours of safety data from the first 2 participants in each group will be reviewed before the rest of the participants in that group may be dosed. After all 8 participants in Group 1 have sufficient safety information, and before Group 2 starts, the safety information from Group 1 will be reviewed by the study doctor and the medical and safety monitors to determine if it is safe to continue. Group 2 will only start if it is safe. The same safety review will occur before the start of the other groups.

The study doctor will talk to you about the things you must do or not do to participate. Please tell your regular health care providers and any emergency care providers that you are in this research study.

As part of your participation in this study, you will be asked to avoid certain prescription medications from 14 days prior to dosing through your Day 56 study visit. You will also be asked to avoid vaccinations (including flu and COVID-19) from 45 days prior to dosing through your Day 56 study visit. Also, you will be asked to avoid non-prescription medications, vitamins, and dietary or herbal supplements from 7 days prior to dosing through your Day 28 study visit. Additionally, there will be certain restrictions on your consumption of beverages containing caffeine or xanthine bases, consumption of alcohol, and use of nicotine-containing products during the study.

Prohibited medications include:

- Immunosuppressives
- Immune modulators
- Oral corticosteroids (topical/intranasal steroids are acceptable)
- Prescription Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
- Anti-neoplastic agents

You must not use any drugs (over-the-counter, prescription, or illegal) without approval from the study doctor. Taking other drugs or alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor you may not be allowed to continue in the study.

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures performed at the Screening Visit to make sure that you are eligible.

Screening does not guarantee entry into the study. Entry into the study will depend upon the results of your lab tests, study specific guidelines, and the judgment of the study doctor. Even if you pass the screening tests, there is a chance that you will not be asked to participate. There may be other reasons why you cannot be in the study. The study doctor and/or the study staff will discuss this with you. You will not be paid for your screening visit(s).

At least two visits to the research facility are required for screening tests. After your first screening results have been reviewed, at least one more screening visit will be scheduled by the

study staff. You will be asked not to consume poppy seeds within 24 hours of the Screening Visit.

Screening Visit
Each participant will undergo an eligibility screening. The following will occur during the Screening Visit:

- Before any study procedures are done, you will provide your informed consent.
- You will be asked about your background and medical history. The study staff will also ask you questions about your age, race, birth control methods, and history of alcohol, nicotine, or drug use in the last 12 months.
- You will be asked about all medicines that you take (including prescription medicines, non-prescription medicines, medications for contraception, vitamins, herbs and supplements).
- You will be asked about your recent vaccinations, including flu and COVID-19.
- You will be counselled to avoid pregnancy.
- You will have a physical exam, including measuring your height, weight, and BMI (a measure which shows whether people have a healthy weight for their height)
- Three ECGs will be performed. An "ECG" or "electrocardiogram" is a test that measures the electrical activity of the heart. A technician will place patches connected by wires to a machine on your chest. The machine records the electrical activity of your heart. This test is performed to ensure your heart is healthy.
- Your vital signs will be measured (blood pressure, heart rate, body temperature, respiratory rate) after ECGs and before blood collections.
- Blood samples will be collected to check for CHIKV (chikungunya virus, which is a mosquito transmitted virus), human immunodeficiency virus (HIV), hepatitis B, and hepatitis C.

As part of this study plan, you will be tested for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome [AIDS]), CHIKV (chikungunya virus, which is a mosquito transmitted virus), hepatitis B and C. You will be informed if any of the testing is positive, and if so, specific counseling will be provided in private. If the test indicates that you are infected with HIV, CHIKV, Hepatitis B or C, you cannot remain in the study and will receive additional counseling about the significance of your care and possible risks to other people. It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right. The study doctor may be required to report all positive results to PPD Austin CRU and the specific Public Health State Department, including your name. The test results will be kept confidential to the extent permissible under the law, though this cannot be guaranteed. For example, it is possible for a court of law to get medical or study records without your permission. If you do not want to be tested for HIV, CHIKV, Hepatitis B or C, then you should not agree to participate in this study.

- Blood samples will be taken in order to check blood cell counts, kidney and liver function, and how well your blood clots.

- Your venous access will be assessed to ensure you have adequate veins for the infusion and blood draws.
- For the initial screening, the amount of blood drawn will be approximately 4 teaspoons (18 mL). It may be necessary to try more than one time if the appropriate amount cannot be collected. Additional blood may be collected to repeat safety tests at the discretion of the investigator. A new needle will be used for each blood draw.
- Female participants will have a pregnancy test (blood sample)
- Post-menopausal women who have not had a regular period for at least 12 months in a row may need to have a blood sample taken to test for the amount of follicle stimulating hormone (FSH). This test is done to make sure that you can no longer become pregnant
- A urine sample will be taken to check for signs of infection, blood, and protein in the urine as well as to test for cotinine (as an indicator for nicotine/smoking) and any drugs of abuse (illegal or prescription) such as:
    - Cotinine
    - Marijuana
    - Amphetamines
    - Barbiturates
    - Cocaine
    - Opiates, etc.
- An alcohol breathalyzer will be performed.

If all inclusion criteria are met and you qualify and agree to continue in this study, you will be asked to avoid extreme physical activity (long distance running or biking, weight lifting, playing contact sports, etc.) from Screening until discharge from the PPD Austin CRU on Day 4.

Day -1 (Admission for confinement to site - through Day 4)
You will be admitted to the PPD Austin CRU one day before you receive study drug. You will stay at the clinic for 4 nights and 5 days. During this admission period, you will be required to stay inside the unit, but you will be free to walk around. There will be television and games for your entertainment. Food will be provided during your stay, except during the periods of time when you will need to fast (not eat). You will not be allowed to have visitors during your admission. If screening tests occurred more than 48 hours before admission, all screening tests will have to be repeated. Women of childbearing potential will be included but will undergo pregnancy testing and be required to use effective contraception from 45 days before study drug administration until 150 days after study drug administration, and the breathalyzer and urine drug screen will have to be repeated for all participants. The following procedures will be done on this study day:

- Your weight will be measured.
- You will be asked about any changes to your health since the screening visit.
- You will be asked about any medicines you are taking or have taken since the screening visit, including your birth control methods.
- Your vital signs will be measured, including blood pressure, heart rate, respiratory rate, and temperature.

- You will have a physical exam, including an evaluation of any infection you may have (this includes questions about your health, medications, recent surgeries, and examining any skin lesions and inside your mouth for dental infections).
- You will give blood and urine for routine lab tests.
    - Some of your urine will be tested for drugs of abuse
    - Some of your urine will be tested to check for signs of infection, blood, and protein
    - Women will have a blood pregnancy test
    - Your blood will be tested to check your general health, including blood cell counts, blood sugar, kidney and liver function tests
    - Approximately 2 teaspoons (12 mL) of blood will be collected at check-in. It may be necessary to try more than one time if the appropriate amount cannot be collected. Additional blood may be collected for a repeat safety test at the discretion of the investigator.
- An alcohol breathalyzer will be performed.
- If all eligibility criteria are met, you may be randomized to receive either SAR440894 or placebo

Study Day 1
On the morning of study Day 1, before getting the study drug, the following procedures will be done:

- You will be connected to ECG telemetry (recording equipment) and will remain connected until about 4 hours after dosing.
- You will have 3 ECGs recorded prior to dosing.
- Your vital signs will be measured including blood pressure, heart rate, respiratory rate, and temperature.
- You will have a symptom directed physical exam as needed.
- An intravenous catheter (IV) will be inserted where the study drug will be infused.
- Another intravenous access point may be inserted to collect blood samples.
- You will have approximately 4 teaspoons (20 mL) of blood drawn to measure the level of study drug in your blood and immune response (before the infusion).
- If you remain eligible and you choose to continue, you may be given a single dose of the study drug (either SAR440894 or placebo).

You will be required to remain lying down from approximately 1 hour prior to infusion until 4 hours after end of infusion. You may use the restroom as needed with the accompany of a staff member. The study drug will be infused over approximately 1 hour. During the infusion, the following procedures will be done:

- Your vital signs will be measured every 15 minutes, including blood pressure, heart rate, respiratory rate, and temperature.
- You will be directly observed by study staff for the duration of the infusion.
- You will have a symptom directed physical exam as needed.

Study Day 1 – Day 3:
After getting the study drug the following procedures will be done:

- Your vital signs will be measured 4 more times on day 1, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have 3 ECGs recorded after dosing on Day 1
- You may have a symptom directed physical exam as needed
- You will give blood and urine sample for routine lab tests each day
- You will have blood drawn 7 more times over days 1-3 (after the infusion) to measure the level of study drug in your blood.

Approximately ¼ cup (56 mL) of blood will be collected between post-dose to day 3.

If you have a hypersensitivity reaction during or after the IV infusion, blood will be collected 3 times after the start of the reaction. The total amount of blood drawn will be 36 mL (a little over 6 teaspoons).

Study Day 4 (Discharge)
The following procedures will be done on this study day:

- You will have 3 ECGs recorded prior to discharge.
- Your vital signs will be measured, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have a complete physical exam.
- You will give blood and urine sample for routine lab tests.
- You will give blood to measure the level of study drug in your blood.
- A total of a little over 3 teaspoons (16 mL) of blood will be collected before you leave the PPD Austin CRU.
- You will be counselled to **AVOID:**
    - pregnancy
    - prohibited medications/substances
    - vaccines
    - use of tobacco or nicotine containing products (smoking, vaping, snuff, etc)
    - excessive caffeine intake
    - extreme physical activity (72 hours PRIOR to Follow-up visits)

Before you leave the PPD Austin CRU , the study doctor will confirm that it is safe for you to leave. Additional procedures may be ordered by the study doctor during the study if necessary, to check your safety. If it is not safe for you to leave the study doctor may ask for you to remain at the site until it is safe for you to leave.

If you experience any changes in health PRIOR to your next visit, report a Study Staff Member by calling the **24-HOUR** number **512-447-2985.**

Study Follow-up Visits: (Days 7, 14, 28, 56, 84, 112)
The following procedures will be done on these study days:

- You will be asked about any changes to your health since the last visit.
- You will be asked about any medicines you are taking or have taken since your last visit
- You will be asked about your method of birth control since your last visit.
- For females, you will be asked about your menstruation.
- Your vital signs will be measured, including blood pressure, heart rate, respiratory rate, and temperature.
- You may have a symptom directed physical exam.
- You will give blood and urine for routine lab tests.
- Women of will have a urine pregnancy test (Days 28 and 84).
- You will give a blood sample to measure the level of study drug in your blood (all visits) and immune response (Days 56 and 112 only)
- You will be counselled to AVOID:
    - pregnancy
    - prohibited medications/substances
    - vaccines (through Day 56)
    - use of tobacco or nicotine containing products (smoking, vaping, snuff, etc)
    - excessive caffeine intake
    - extreme physical activity (72 hours PRIOR to Follow-up visits)

For each follow-up visit, approximately 4 teaspoons (20 mL) of blood will be collected. For your safety, if lab test results are not normal, you may be asked to return to the Austin PPD CRU to have more blood and/or urine samples be collected.

End of Study Visit: Day 150
The following procedures will be done on this study day:

- You will be asked about any changes to your health since the last visit
- You will be asked about any medicines you are taking or have taken since your last visit.
- You will be asked about your method of birth control since your last visit.
- For females, you will be asked about your menstruation.
- Your vital signs will be measured, including blood pressure, heart rate, respiratory rate, and temperature.
- You will have a complete physical exam.
- You will have 3 ECGs recorded.
- You will give blood and urine for routine lab tests.
- Women will have a urine pregnancy test.
- You will give a blood sample to measure the level of study drug in your blood and immune response.
- Approximately 4 teaspoons (20 mL)of blood will be collected.

During the study, you will have your blood drawn about 24 times. Approximately 1 ½ cups (315 mL) of blood may be drawn during this study. This includes blood drawn for hypersensitivity reaction. For comparison, the standard blood donation is about 2 cups (480 mL).

You must also allow PPD Austin CRU to use any unused blood samples collected for clinical labs for calibration of lab equipment and the establishment of lab references and normal ranges.

Unscheduled Visits
You may be asked to come back to the study clinic at other times if the study staff feels there is a need to do so. The study staff will determine what activities will be necessary, but at a minimum will review with you any symptoms you are having, review your medications, and perform vital signs and a symptom directed physical exam if appropriate.

Early Withdrawal from the Study
You may be withdrawn from the study before completion, even if you want to continue. If you are withdrawn from the study due to safety reasons, you will be discharged from the unit only when the study doctor feels that it is safe to do so. If you stop the study early for any reason, the study doctor will ask you to perform the evaluations that are typically performed on Day 150 (End of Study Visit). You will also be counselled to avoid pregnancy and prohibited medications/substances until 150 days have elapsed from receipt of study drug.

Your participation in the study may be stopped for any of the following reasons:

- Failure to follow the study requirements, including use of effective birth control
- Non-compliance with study specific instructions provided by study doctor or study staff
- Behavioral issues that interfere with study requirements or study staff
- The study doctor decides it is in the best interest of your health and welfare to discontinue
- At the request of your primary care provider
- The Food and Drug Administration (FDA), other regulatory agencies, or the sponsor (NIH/NIAID) who oversee the conduct of this study can stop the study at any time for safety concerns or other issues.

You may also decide to stop your participation in the study at any time and this will not affect your relationship with PPD Austin CRU or the sponsor.

HOW LONG WILL I BE IN THIS STUDY?
If you choose to participate in this study, your participation is expected to last up to 5 months, not including up to 4 weeks for screening.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your study doctor first.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

It is very important that you tell the study staff immediately about any side effects. It is also very important that you do not talk to other subjects about your side effects or theirs.

If you do not tell the study staff about a side effect, or if you talk to other subjects about your side effects, you may be removed from this study. In addition to being removed from the current study, your payment may be reduced, and you may not be allowed to take part in future studies for PPD.
All side effects or changes in your normal health must be reported, even those changes you might not consider to be important. Some examples may include:

- Headache
- Tooth pain
- Bruising
- Hiccups
- Changes in your eating or sleeping patterns.

BECAUSE THIS IS THE FIRST TIME THIS STUDY DRUG IS BEING GIVEN TO HUMANS, NOT ALL OF ITS SIDE EFFECTS ARE KNOWN.

If you have any changes in your health/medical history after signing and dating this consent document, please report to your study doctor or study staff.

One of the reasons for this study is to learn more about the possible side effects of the study drug(s). It is important that you tell the study staff about possible side effects. Contact PPD if you experience any side effects through 150 days after your last dose of study drug.

Rare or unknown side effects could possibly occur, including allergic reactions, and life-threatening reactions.

You may harm yourself by taking part in this study if you are not fully truthful about any side effect with the study doctor and study staff.

Risks of SAR440894
Because SAR440894 is considered "investigational," complete information about the safety of SAR440894 is not yet available. This is the first clinical study of SAR440894 in humans. When SAR440894 was given to mice, the animals had a mild to moderate, temporary increase in the amount of protein and blood in the urine, which may reflect kidney injury. However, when SAR440894 was given to non-human primates, these animals did not have any study drug-related changes in their urine or kidney function. During the course of the study, your kidney function will be closely monitored by blood and urine collection. At this stage of development, there is no evidence that the study drug is unsafe when given to people; however, there could be additional risks, including death, that are not yet identified.

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.

SAR440894 may cause some, all or none of the side-effects that were previously reported, in the use of similar drugs, including:

- Life threatening allergic reactions
- Fever
- Chills
- Shivering
- Nausea
- Vomiting
- Pain
- Headache
- Dizziness
- Shortness of breath
- Tightening of airway
- Low blood pressure
- High blood pressure
- Itchy skin
- Rash
- Hives
- Swelling
- Diarrhea
- Chest pain

You should discuss these with the study doctor and your regular health care provider if you choose.

As with other monoclonal antibodies, hypersensitivity (allergic or autoimmune) reactions including anaphylaxis (severe allergic reaction) may occur immediately or within a few hours of infusion. This may be related to the generation of antibodies your body creates which are directed against SAR440894 (antidrug antibodies). This immune response will be measured by taking blood samples at selected visits throughout the study. In animal testing, no antidrug antibodies were detected in any animals given SAR440894. In addition, infusions of monoclonal antibodies may be associated with infusion reactions including allergic reactions. These types of reactions would cause fever, chills and shivering, typically occurring within the first two hours following infusion. Other symptoms sometimes associated with infusion reactions include:

- Nausea
- Vomiting
- Pain
- Headache
- Dizziness
- Shortness of breath

- Spasms in the airway to the lungs or other acute lung response
- Low or high blood pressure
- Itching
- Rash
- Hives
- Swelling in the tissues of your body
- Diarrhea
- Tachycardia (abnormally fast heart rate)
- Chest pain

Allergic reactions may be mild but can also be severe and life-threatening. Please alert the study doctor and study staff immediately if you have any of these symptoms, or any other side effects, during the study.

There is also a risk that you may experience a delayed hypersensitivity or immune response. Symptoms may include:

- Delayed onset of fever
- Rash
- Joint pain
- Muscle pain
- Blood or protein in your urine
- Inflammation of your body tissues
- Nervous system complications
  Hemolytic anemia (a disorder in which red blood cells are destroyed faster than they can be made)

None of the animals tested so far has shown any negative impact to their immune function. Participants with any present or recent evidence of CHIKV infection or at risk for infection are not eligible for the study.

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.

Co-Occupancy During Confinement

There is an increased risk to COVID due to co-occupancy. For this reason, there will also be required additional testing that is explained below.

1. Pre- admission:
   a. You will need to pay close attention to all COVID precautions, including masking, limiting contact with others, limiting travel, and maintaining social distancing as per site standards.
   b. You will have a COVID test on the day of admission for the confinement period.
   c. You will be provided clear instructions regarding confinement expectations.

2. During confinement you will:
   a. Immediately isolate and report development of new symptoms concerning for COVID
   b. Undergo COVID testing as per PPD Austin CRU standards.
   c. May be required to eat and drink only in your assigned room.
   d. May be required to wear site provided mask unless eating, drinking, or sleeping.
   e. May be required to remain at least 6 feet apart from others when not wearing a mask.
   f. May be required to remain in your room unless scheduled time in the lounge area and only go there with your roommate. Lounge time will be allocated so that you will remain with the same group during the confinement period in order to minimize exposure to others.
   g. Perform hand hygiene with soap and water or approved hand sanitizer frequently.
   h. Wipe down shared high touch surface areas after use – such as the washing machine, lounge table, remote control, sink handles, etc.
   i. Be discharged to home for isolation and close observation should your COVID test become positive.

3. Post-confinement:
   a. You will require quarantine and COVID testing post-exposure as determined by PPD Austin CRU standards if you are exposed late during your confinement period.

COVID-19 test requires a nasal or nasopharyngeal sample that will be taken from your nostrils to check for any organisms or to determine any presence of COVID-19 infection. There may be side effects such as:

- Sneezing
- Eye watering
- Nosebleeds

IV Catheter Placement and Infusion

A small needle with a thin plastic tube covering it (like a small straw) called a "cannula" will be inserted into a vein in your arm or hand. A study staff member puts the needle with the cannula over it into a vein in your arm or hand, and then slides the cannula over the needle into your arm or hand vein. The cannula stays in your arm or hand vein, and the needle is taken out. The cannula is used as a way to get the IV study drug into your vein. The cannula will remain in your

arm until after end of infusion. Another cannula may be put in the other arm or hand that is not being used to give you the study drug for collecting blood samples. This is not always needed, and the study doctor will decide if it is needed and discuss this with you. You will need to keep your arm very still anytime that you are getting the study medication through the vein in your arm and while the cannula is in your arm. Very small amounts of saline (salt water) solution will be injected into this cannula to keep the vein open. This will be done before the start of the IV infusion and at other times during the study. You may have pain, swelling and redness at the place where the cannula is put into your vein. When a cannula is used for blood collection, we will take about an extra 1 mL (less than ¼ of a teaspoon) of blood.

An IV catheter may cause an inflammation in a vein (phlebitis) with signs of redness and warmth at or near the IV insertion site. Inflammation in a vein due to a blood clot (thrombophlebitis) is also a potential risk. This would be a hard area the study doctor could feel near the IV insertion site. These risks are minimal as the infusion time is around one hour. There is the potential for leakage of the study drug into the tissues surrounding the IV site. There is a risk of infection; however, this is a small risk as aseptic technique will be employed.

Risks of Using an Intravenous (IV) Catheter:

- Infection
- Pain
- Redness
- Bruising
- Local swelling due to IV fluid accidentally entering the tissue rather than the vein.
- Blood clots, which may cause inflammation, swelling and pain.

Catheter Insertion Risks/Blood Samples
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible. A temporary needle with catheter may be placed into your vein during the study to collect blood. This decreases the amount of needle sticks you would receive during these days. The study staff will keep the blood draw area clear and clean. Participants may feel pain or experience bruising at the site where the blood is drawn or the catheter is inserted. There is a risk of participants feeling dizzy and/or fainting. Infection at the site of the blood draw or catheter insertion is possible. Some minor discomfort may be felt when blood is drawn from the veins (or the catheter inserted) in your arm.

You will be required to provide blood samples during the study. The total amount of blood collected over the duration of the study, including any extra assessments that may be required, will not exceed 450 mL (about 2 cups). This is less than you would give during a regular donation to a blood service agency.

ECGs and Blood Pressure Risks
Electrocardiograms (ECGs) (electrical tracings of the heartbeat or heart rhythm) will be done during this study in which you will have adhesive pads placed on different parts of your body. There is no pain or discomfort during an ECG; however, removing the pads may cause some

redness or itching to your skin. You may experience bruising from the blood pressure cuff. Discoloration of the skin at the pad sites may occur and could persist for an indefinite length of time. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Reproductive Risks

For Women: The effects of the study drug on a developing pregnancy or breastfeeding infant are not known. Drug taken in this study may be transferred into human milk and may pose a risk to your baby Therefore, women who are pregnant, planning a pregnancy, considering an egg donation, or breastfeeding are excluded from the study.

If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy [removal of uterus] and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a blood pregnancy test will be done and it must be negative in order to participate. In women 40 years old and older, blood pregnancy tests may sometimes give a false positive or "indeterminate" result and additional testing may be required to confirm your eligibility for the study. Additional urine pregnancy testing will be done at subsequent visits as described above and must be negative for you to continue in the study.

It is **very** important that you not become pregnant or breastfeed during this study. If you and your partner are having vaginal intercourse and you are of childbearing potential, you must use an effective method of contraception from 45 days before study drug administration until 150 days afterwards. Effective methods include:

1. Exclusive non-male sexual relationships
2. Monogamous relationship with vasectomized partner (greater than or equal to 180 days between procedure and receipt of study drug)
3. Bilateral tubal ligation (tubes tied) or tubal occlusion (tubes blocked) (Essure®)
4. Effective intrauterine device (IUD)
5. Hormonal implants (Implanon®)
6. Other hormonal contraceptives (such as birth control pills, vaginal rings, patches or injections)
7. Barrier method (condom, diaphragm, cervical cap) PLUS spermicide (gel or foam) with perfect use.

If you have questions about methods, your study doctor will discuss options with you, given your personal preferences and the level of effectiveness required by this study.

Because no birth control method is 100% effective, you should notify the study team immediately if you think there is any chance you could be pregnant within 150 days after the study drug administration. There is a chance that a pregnancy test could indicate that you are not pregnant, even though you are. **If it is early enough in your pregnancy, a pregnancy test may not be able to detect that you are pregnant.**

If pregnancy is confirmed, the study team will ask your permission to collect information on your health during the pregnancy and, if appropriate, on the health of the baby for up to 6 weeks after birth. You will be requested to consult with your study doctor regarding the risks to your unborn baby and you (female subjects) will be requested to be followed-up by the study doctor at least until the baby is born to assess possible complications.

For Men: The effects of the study drug on a developing pregnancy that began while the father was taking the study drug are not known. In addition, the study drug may be present in semen and transmitted to a partner during sexual activity. If you and your partner are having vaginal intercourse and your partner is of childbearing potential (she has not completed menopause, or she has not had a hysterectomy and/or both tubes and/or both ovaries removed), you must use an effective method of contraception from 45 days before study drug administration until 150 days afterwards. This is true even if you have had a vasectomy (because vasectomy does not prevent transmission of study drug in semen) or your partner is using another method of birth control. If your partner is pregnant or breastfeeding, you must use a condom for all types of intercourse.

You should inform your partner about your participation in this study and the potential risks to a pregnancy. If she does become pregnant within 150 days after study drug administration, you should notify the study team.

Your partner may be asked for her permission to collect information on her health during pregnancy and, if appropriate, on the health of the baby for up to 6 weeks after birth.

You also must agree not to donate sperm for the duration of the study.

General Discomforts and Study Restrictions
You will be asked to fast during parts of this study. This may cause you some discomfort. In addition, study requirements such as overnight stays at the clinic, dietary restrictions, medication and vaccine restrictions, restrictions on blood donation, and limitations on caffeine (no more than 400 mg per day within 1 week of screening and during the study), alcohol (none within 24 hours of dosing), and smoking or use of nicotine-containing products including, but not limited to vaping, patches, and gum (none within 45 days before study drug administration through the final study visit) may also cause you some discomfort.

Digital Photos: In the event of any physical finding or adverse event (for example, an injection site reaction of redness, bruising or swelling), the study doctor may request digital photos be taken of the areas. The photos will be taken in a manner so that there is no way you could be identified in the pictures. If DMID staff and/or people working on behalf of DMID need to look at and review the photos, they will be shared with them while keeping your personal information private. See section “WILL MY INFORMATION BE KEPT CONFIDENTIAL?” for more details on how we will handle capturing, storing, and sharing your information from this study.

Serious adverse reactions and hospitalization
Although all possible precautions are taken to prevent serious adverse reactions (side effects), if such an event occurs, it may be in your best interest to be admitted to hospital. Depending on the type of reaction, we may contact a medical specialist to be primarily responsible for your

treatment. We will provide assistance to the hospital and doctors looking after you, but all hospital records are confidential and for this reason we are asking you to give us, and any emergency medical specialists we contact, consent to visit you and have access to your medical records.

Drug Interactions
For your safety, you must tell the study doctor or study nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there will be no direct medical benefit to you. We hope the information learned from this study will benefit others in the future.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information (such as name, address, date of birth, etc.) may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. The following people will have access to your study records:

- Study doctor and study staff
- Study Monitor
- Sponsor company [including monitor(s) and auditor(s)]
- People who are collaborating, funding, and regulating the study
- The Food and Drug Administration (FDA)
- Other country, state, or federal regulatory agencies
- Advarra IRB

We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, and procedures may be reported to the NIH, Division of Microbiology and Infectious Diseases (DMID), and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of DMID, the PPD Austin CRU, Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain laboratory tests and/or other procedures performed. These test results will be recorded in your medical record and will be reported to the representatives and affiliates of DMID. Your information will be stored on password-protected computers. Research samples and data will be linked to you using an assigned study code. The code does not include your name or other information that could be used to easily identify you. A code key links the samples and information with your name and contact information. Access to the data, samples and sample code keys is limited to people working on this study and to those who provide oversight.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the study doctors may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. You have consented to the disclosure, including your medical treatment; or
3. The research information is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the study doctor is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All of the blood, urine, and ECG studies are being done only because you are in this study. The study results will not routinely be provided to you OR sent to your regular doctor. No genetic testing will be performed on your samples in this study.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at the PPD Austin CRU. Any research information in your medical record will be kept indefinitely.

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your study doctor(s) decide that it is necessary for your care.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of the PPD Austin CRU we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

If PPD is notified that you have participated in a research study at another research facility while also participating in a research study at PPD, it may be necessary for PPD to share certain details about your study participation with the other research facility.

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

WHAT ARE THE COSTS TO YOU?

While you are in the study, you may still need to get routine medical care. You (and/or your health care payer) will still have to pay for the costs of your routine medical care that are not part of this study.

There will be no costs to you for being in this study. You will not have to pay to receive the study drug. There are also no costs for the tests or procedures performed as part of the study.

We will monitor your PPD Austin CRU participant care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
For the current study, you will receive:

> $750.00/night for each night that you spend at the research facility ($750.00/night x 4 nights x 1 study periods).
>
> $650.00/visit for each outpatient visit to the research facility ($650.00/visit x 7 outpatient visits x 1 study periods).

If you successfully complete the study, you will receive an additional $1,450.00 making your total payment $9,000.00. You will receive final payment within 3 weeks of your last study visit or your study completion.

If you have a side effect linked to the study drug and the study doctor thinks that this may harm your safety, you will be taken out of the study. You may be paid in full, including the study completion bonus, at the discretion of the study doctor. However full payment is not guaranteed. If you have a side effect linked to the study drug and you leave the study when the study doctor does not think your safety is at risk, your pay will be lower. You will receive a pro-rated payment and pro-rated study completion bonus based on the days you were in the study. If the study doctor releases you from the study and it is non-drug related, you will receive a pro-rated payment and pro-rated study completion bonus based on the number of days you were in the study.

If you are a backup subject who is required to stay in the facility overnight, you will be paid $250.00. If you are not required to stay overnight you will be paid $100.00. If you are required to stay for additional nights for safety procedures or observation, then you will be paid $650.00 for the additional night(s).

You will be paid an amount based on the extent of your participation, if:

- You are unable to complete the study
- You miss multiple outpatient visits (your completion bonus will be reduced accordingly)
- You voluntarily leave the study
- The study doctor withdraws you early from the study
- The study is stopped early
- You are qualified but not chosen to participate

If you withdraw from the study, you will still receive compensation for the parts of the study you completed based on the number of nights spent in the facility and number of outpatient visits completed.

You will be expected to read and follow the Phase 1 Clinic Subject Rules and Regulations, available at http://www.ppd.com, while participating in the study. If you do not have access to the internet, let a PPD study staff member know and you will be provided with a printed version to review. The study staff will be available to answer any questions or clarify any information you do not understand. You will be asked to confirm whether you have fully read the Rules and

Regulations document, acknowledge that you have been given the opportunity to ask questions and that you have received satisfactory answers. If you do not read and acknowledge the Rules and Regulations document, you will not be able to participate in the study. If you do not follow the Rules and Regulations of the Phase I Clinic during your participation in the study, you may not be paid as stated above.

If at any time you test positive for drugs or substances other than the study drug or if you engage in disruptive behavior, you may not be paid as stated above. Disruptive behavior includes, but is not limited to:

- Destruction of property
- Stealing
- Verbal abuse or profanity
- Bodily or verbal threats
- Sexual harassment

If you engage in disruptive behavior, or if you test positive for drugs or substances other than the study drug you will be paid $2.00 per night and/or outpatient visit for the time you were in the study. You will immediately be dropped from the study. Also, you may not be allowed to take part in other studies for PPD.

If you feel that the payment listed may interfere with your making a good decision about whether or not you should volunteer to be in this study, you should not agree to participate.

Payment received as compensation for participation in research is considered taxable income to the research participant. You have to provide your social security number or ITIN because the IRS may be told how much you were paid to take part in this study. A study staff member will enter the number into our database where the number is immediately suppressed from view and cannot be accessed by general staff. Access to your social security number or ITIN is limited to finance in order to process payments and report taxable income to the IRS. If payment to an individual exceeds $600 in any one calendar year, the PPD Austin CRU is required to report this information to the Internal Revenue Service (IRS). Research participant payments to a non-employee of PPD Austin CRU exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at the PPD Austin CRU in the event that you are injured as a result of your participation in this research study. While you are in this study, if you are injured due to activities unrelated to study, personal conduct or unauthorized activities which are not part of this study, you will not be compensated for such injuries. In addition, no long term medical care or financial compensation for research-related injuries will be provided by PPD, the NIAID NIH or the federal government.

In the event you require treatment at a medical facility other than PPD during the study, PPD may need to provide your study records, which may include demographic and/or personal information, to the healthcare provider involved in your care or treatment. There may also be the

event where you have test findings (such as lab reports or ECGs) or certain side effects where the study doctor thinks it is necessary to consult with an outside specialist doctor about those findings. If an outside specialist doctor is consulted, PPD may need to provide your study records, which may include demographic and/or personal information, to that specialist doctor. The information disclosed to the healthcare providers at the medical facility or the outside specialist doctor may include records/reports including but not limited to clinical lab reports, ECGs, vital sign measurements and information related to ongoing side effects and/or concomitant medications (other medications taken while taking study drug or placebo).

As part of this coordination of care, the healthcare providers at the medical facility or the outside specialist doctor's office will provide the PPD study doctor and study staff with information about your care, including copies of medical records related to your care.

For questions about the study or research-related injury, contact the Jessica Leos (Clinical Research Manager) or Kristie Miller, M.D. at 512-447-2985 during regular business hours, after hours, and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. No one can force you to be in the study. You can leave the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at the PPD Austin CRU. If you do decide to withdraw, we ask that you contact the Jessica Leos (Clinical Research Manager) or study staff and let them know that you are withdrawing from the study.

The study doctor may ask you to complete the tests that would ordinarily occur when a person completes the study.

Kristie Miller, M.D.
PPD Development, LP
7551 Metro Center Drive, Suite 200
Austin, Texas 78744.

Dr. Miller may ask you to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your study doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified, and your study doctor will discuss other options with you.

You may be taken 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 it is discovered that you do not meet the study requirements (including any requirements in this consent document)
- If the study is cancelled
- If it becomes harmful to your health
- If you are not truthful
- If the study physician feels it is in the best interest of your health and/or safety

We will not use your information or samples in other research, even if codes that can identify you are removed.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM TO CONTACT ABOUT THIS STUDY

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

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or PPD Austin CRU decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00074054.

ELECTRONIC SURVEILLANCE
The facility is equipped with electronic surveillance and your activities may be monitored.

AGREEMENT TO BE IN THE STUDY

This consent document contains important information to help you decide if you want to be in this study. You have been informed and explained the purpose of this study, procedures to be followed, risks and benefits. You have been told whom to contact if you have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. If you have any questions that are not answered in this consent document, please ask one of the study staff.

By signing and dating this informed consent document, you are acknowledging that you can read, understand, and speak English, that you understand the information in this consent document. You have had an opportunity to ask questions of study staff and / or a medical professional in a one-on-one setting and received satisfactory answers to all your questions about this study. You acknowledge that you have not completed any study procedures prior to signing and dating this consent document. You understand that you are free to leave the study at any time without having to give a reason and without affecting your future participation in studies. You understand that your study-related medical records may be reviewed by the company sponsoring the study and by government authorities. You voluntarily agree to allow study staff to collect, and share health data as specified in this form.

You will receive a signed and dated copy of this consent document.

You are not giving up any of your legal rights by signing this form.

A graphical representation of your signature will be electronically captured if you agree to participate. The graphical representation of your signature is equivalent to your legal signature.

IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE, YOU SHOULD NOT SIGN AND DATE THIS INFORMED CONSENT DOCUMENT.