INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

Sponsor / Study Title:	**Pfizer Inc / "A PHASE 1, RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO-CONTROLLED, PARALLEL STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF MULTIPLE ASCENDING ORAL DOSES OF PF-07328948**
Protocol Number:	**C4921002**
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INTRODUCTION

You are here today as a possible participant in a drug research study sponsored by Pfizer Inc. Taking part in this study is voluntary (your choice). The study staff will be available to answer questions before, during, and after the study.

The sponsoring company (the company paying for this study), Pfizer Inc, employs the study investigator conducting this study.

If you are not completely honest about your health history, you may be harmed by being in this study.

PURPOSE OF THE STUDY

PF-07328948 will be referred to as the "study drug" in the rest of this consent document.

The purposes of this study are:

PART A

- To see how a new drug under study is tolerated, if there are significant side effects, and how healthy non-Japanese and Japanese adults (if enrolled) people feel after taking multiple increasing oral (by mouth) doses
- To measure how much of the study drug is in your blood and urine after taking multiple doses
- To check the effect of multiple increasing doses of the study drug on substances in the body that are involved in the body's metabolism under fasting (without food) and/or fed (with food) conditions
    - These substances may include:
        - Blood levels of branched-chain amino acids (BCAA)
        - Blood levels of branched-chain α-keto acids (BCKAs)

    - If dosing under fed conditions, the meal may be a standard breakfast or a protein rich meal
        - Ensure Plus® is an example of the type of protein rich meal that could be given
- To check the effect of multiple increasing doses of the study drug on enzymes (CYP3A) and proteins (organic anion transporters)

PART B (Optional)

- To see how the tablet and liquid formulations are tolerated, if there are significant side effects, and how healthy adults feel after taking single oral doses
- To measure and compare the amount of study drug in your blood after a single oral dose of the tablet and liquid formulation
- To check the effect of a high-fat meal on the amount of study drug in your blood after a single oral dose of the tablet formulation
- To measure the amount of study drug-related material in your urine and feces after a single oral dose (Period 1, Dosing Sequence 1 only)
- To identify metabolites in your blood (if needed), urine, and feces (Period 1, Dosing Sequence 1 only) after a single oral dose, if possible. Metabolites are bi-products or end products of a drug produced as the body processes a drug

This will be the first time that multiple doses of this study drug will be given to humans.

The study drug is a new investigational drug being studied to treat people with heart failure. Heart failure is a disease that affects the pumping action of the heart. It can cause fatigue and shortness of breath. "Investigational" means that the drug has not been approved by the United States (US) Food and Drug Administration (FDA). Study drug and placebo will be given as a suspension (a liquid) which you will drink or as a tablet(s).

The placebo looks like the study drug but does not contain any active ingredients. Researchers will compare the results of taking the placebo to the results of taking the study drug to see if there are any differences.

Part B, Dosing Sequence 1, Period 1

A dietary fiber supplement may also be given in this part of the study to ensure regular bowel movements. Prune juice and a stool softener (docusate) or mild laxative (milk of magnesia) may also be given to ensure a daily bowel movement during fecal sample collection.

ABOUT THE STUDY

Number of Study Participants

PART A

There will be up to 96 people taking part in this part of the study.

Length of Study for Participants

You will be in this study for about 44 days. This does not include the time between screening and dosing, which can be up to 28 days.

This part of the study involves:

- 1 dosing period with 18 overnight stays at the Clinical Research Unit (CRU). You will not be able to leave the CRU during that time
- 1 follow-up visit to the CRU about 7 days after the last dose
- 1 follow-up phone call about 4 weeks after the last dose

PART B (Optional)

There will be up to 12 people taking part in this part of the study.

Length of Study for Participants

Dosing Sequence 1

You will be in this study for about 49 days. This does not include the time between screening and dosing, which can be up to 28 days.

This part of the study involves:

- 3 dosing periods during 1 continuous admission.
- 23 overnight stays at the CRU. You will not be able to leave the CRU during that time
- 1 follow-up visit to the CRU about 7 days after the last dose
- 1 follow-up phone call about 4 weeks after the last dose

There will be at least 10 days between dosing in Period 1 and Period 2, and at least 7 days between dosing in Period 2 and Period 3.

Dosing Sequence 2

You will be in this study for about 44 days. This does not include the time between screening and dosing, which can be up to 28 days.

This part of the study involves:

- 3 dosing periods during 1 continuous admission
- 18 overnight stays at the CRU. You will not be able to leave the CRU during that time
- 1 follow-up visit to the CRU about 7 days after the last dose
- 1 follow-up phone call about 4 weeks after the last dose

There will be at least 7 days between each dose.

Eligibility to Participate in Another Drug Study

Your eligibility to take part in another study depends on information from this study and the previous study. You may be eligible to receive a different study drug in another study as soon as 30 days after your last dose of study drug in this study. This is true for most drugs. Some drugs may stay in your body longer which means that you may have to wait longer before joining another study. These results are usually known after your last blood sample is tested. We will tell you this as soon as possible. We will also tell

you if there is a longer than usual period of time that you should not be in another drug study after this one. Our goal is to keep you from doing anything that might potentially harm you.

Dosing Plan

The dose of the study drug that will be used to treat people is not yet known.

PART A

Up to 10 groups of participants are planned.

The dose of study drug will start at 50 mg given twice a day for the first group of participants. The dose may increase for subsequent groups, but will not exceed a total daily dose of 1500 mg. The dose will only increase if it is believed to be safe. How well the study drug is tolerated, blood tests, and information from the previous ongoing study and dosing groups in this study will help us to decide if it is safe.

Doses may be changed based on study drug safety, blood levels, information from the previous ongoing study, or previous dosing groups in this study. Up to 2 additional dosing groups of 10 non-Japanese participants each may be added. Doses on Days 1, 7 and 14 may also be given under fasting conditions.

Dosing is planned as follows:

DOSING GROUP	**NUMBER OF PARTICIPANTS**	**STUDY DAYS** **1 – 14***
1	10	50 mg of study drug or placebo given twice a day
2	10	300 mg of study drug or placebo given once a day
3	10	50 mg of study drug or placebo given once a day
4	10	100 mg of study drug or placebo given once a day
5	10	300 mg of study drug or placebo given once a day
6	10	750 mg of study drug or placebo given once a day
7	10	1,500 mg of study drug or placebo given once a day
8+	10	TBD mg of study drug or placebo given once a day
9+	10	TBD mg of study drug of placebo given once a day
10@	6	TBD mg of study drug or placebo given once a day

* Only the morning dose will be given on Day 14 if dosing twice a day
+ Optional groups
@Optional group of Japanese participants
TBD – to be determined

The doses that you receive are compounded in our pharmacy for use in this part of the study. Compounded means that the ingredients are added together and mixed to make the final dose(s).

If you are in dosing group 1- 9, you have about a 1 in 5 chance of receiving placebo during the study. If you are in dosing group 10 (if done), you have about a 1 in 6 chance of receiving placebo during the study.

Both you and the study staff will not know whether you are receiving the study drug or placebo. In case of a medical emergency, the study investigator can find out what you have received if considered necessary.

If dosing twice a day, on study Days 1 – 13 you will receive a single oral dose of study drug or placebo twice a day. On study Day 14, only the morning dose will be given.

If dosing once a day, you will receive a single oral dose of study drug or placebo in the morning.

Morning doses will be given after eating a standard breakfast or drinking Ensure® Plus (Day 1, 7, and 14). As noted above, doses on Day 1, 7, and 14 may be given under fasted conditions. Breakfast will be served about 30 minutes before dosing. Ensure® Plus will be provided about 20 minutes before dosing. Breakfast should be completely eaten within 20 minutes. Ensure® Plus should be completely swallowed within 10 minutes. Dosing will follow within 10 minutes of completing breakfast or drinking Ensure® Plus or similar protein rich meal.

Morning doses on Days 1, 7, and 14 may be given under fasting conditions (if needed), after an overnight fast of at least 10 hours.

PART B (Optional)

One group of participants is planned.

Dosing is planned as follows:

DOSING SEQUENCE	**NUMBER OF PARTICIPANTS**	**STUDY PERIOD**		
		1	**2**	**3**
1	6	Study Treatment A	Study Treatment B	Study Treatment C
2	6	Study Treatment B	Study Treatment A	Study Treatment C

Study Treatment A: Single dose of study drug given as an oral suspension under fasting conditions
Study Treatment B: Single dose of study drug given as a tablet(s) under fasting conditions
Study Treatment C: Single dose of study drug given as a tablet(s) under fed conditions

The doses in this part of the study are to be determined based on information from Part A of the study.

Your study treatment sequence will be randomly assigned like pulling a number out of a hat.

The liquid dose that you receive is compounded in our pharmacy for use in this part of the study. Compounded means that the ingredients are added together and mixed to make the final dose.

Both you and the study staff will know which study treatment you are receiving.

On Day 1 of each period, you will receive a single oral dose of study drug. You will fast overnight (nothing to eat or drink except water) for at least 10 hours before dosing or eating a high-fat breakfast.

An example of a high-fat breakfast includes: 2 eggs fried in butter, 2 strips of bacon, 2 slices of toast with butter, 4 oz of hash brown potatoes, and 8 oz of whole milk. All of the breakfast should be eaten within 20 minutes. If you agree to be in this study, you are agreeing to eat all the food listed in this menu.

PART A & B

Each dose will be taken with water. The total volume of fluid of the liquid dose and water will be about 8 oz (1 cup). Tablet(s) will be taken with about 8 oz of water and must be swallowed whole. We will check your mouth after each dose to make sure the study drug or placebo has been swallowed.

This is a research study. The study drug and, if given, dietary fiber supplement, prune juice, stool softener, and milk of magnesia will be given to you only during this study and not after the study is over.

Study Process

Before any study procedures begin, you will be asked to read, sign, and date this consent document.

Screening

After you sign and date the consent document, you will begin screening. The purpose of the screening is to find out if you meet all of the requirements to take part in the study. Procedures that will be completed during the study (including screening) are described below. If you do not meet the requirements, you will not be able to take part in the study. The study investigator or study staff will explain why.

As part of screening, you must complete all of the items listed below:

- Give your race, age, gender, and ethnicity
- Give your medical history
    - You must review and confirm the information in your medical history questionnaire
- Give your drug, alcohol, and tobacco use history
- Give your past and current medication and treatment history. This includes any over-the-counter or prescription drugs, such as vitamins, dietary supplements, or herbal supplements, taken in the past 28 days
- Height and weight will be measured
- Physical exam will be done
    - This may be done at screening or when you check-in for the study
- Vital signs (blood pressure and heart rate will be measured)
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- COVID-19 procedures:
    - You may be asked to complete a COVID-19 questionnaire
    - You may be tested for COVID-19 at each visit to the CRU
        - COVID-19 testing will be done by collection of a swab sample
    - Staff may be wearing masks, face shields, respirator hoods, gowns, and gloves
    - You may be required to wear a mask at all times. If required, it will be provided to you
- Safety lab tests will be done from blood and urine samples. In addition:
    - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C

        - Part A only
            - Blood tests to see how your blood clots and if you have any findings that indicate you may be at higher risk for developing a blood clot
                - ✓ Anti-phospholipid antibodies (proteins)
                - ✓ PT/aPTT
                - ✓ D-Dimer
                - ✓ Protein C activity
                - ✓ Protein S (activity and antigen)
                - ✓ Antithrombin activity
                - ✓ APC resistance
                - ✓ Fibrinogen
    - Urine to test for drugs of abuse (illegal and prescription)
    - Females who have not had a period for at least 12 months in a row will have a blood hormone test to confirm they cannot have children
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed (males only)
- You will be asked "How do you feel?"

HIV and Hepatitis Testing

HIV, hepatitis B, and hepatitis C will be tested at screening. If anyone is exposed to your blood during the study, you will have these tests done again. If you have a positive test, you cannot be in or remain in the study.

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). If your HIV test is positive, you will be told about the results.

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

Having certain infections or positive test results may have to be reported to the State Department of Health. This includes results for HIV, hepatitis, and other infections. If you have any questions about what information is required to be reported, please ask the study investigator or study staff.
Although this testing is meant to be private, complete privacy cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

During the Study

The events below will take place throughout the study. If you would like to know when exactly these will take place, please ask the study staff.

- You will be asked about any updates to your medical history. This includes medication, drug, alcohol, and tobacco use
- Physical exams, including neurological exam (to see if your nervous system is normal), and focused clinical exams to check for blood clots (Part A only)
- Weight will be measured
- The use of proper birth control will be confirmed/reviewed (males only)
- Vital signs, including breathing rate (Part A only), will be measured. Your oral temperature may also be measured

- ECGs will be collected
    - It may be necessary to shave or trim hair on your chest so that the patches for the ECGs will stick to your skin
    - Your chest may be marked with a pen to identify the correct areas for ECG patch placement
- Continuous heart monitoring will be done for at least 8 hours after morning dosing on Days -1, 7, 10 and 14 (Part A only). There will also be a period of at least 2 hours (Day -1) where monitoring will be done before the first dosing
    - This involves the attachment of a small box like unit (transmitter) to your chest
    - The box is attached by a few wires (similar to those of an ECG)
    - The monitor sends information about your heart's activity by a radio signal to a monitor
    - You may not sleep during the 2 hours of continuous monitoring done before dosing
    - You will need to stay in the procedure room for at least 4 hours after dosing while attached to the monitor
    - You will need to keep the box with you during the monitoring period
    - You will be asked to minimize activity while attached to the monitor
- You will be asked: "How do you feel?" each day
- An intravenous (IV) catheter may be placed in a vein in one of your arms for blood collection
- The study investigator may decide to do an alcohol breath test at any time
- You may complete a COVID-19 questionnaire
- You may be tested for COVID-19
- Blood and urine samples will be collected at various times throughout the study
    - Safety Labs: The blood and urine samples will be used for safety labs including the following:
        - Urine samples to test for drugs of abuse
        - Blood tests to see if you may be at higher risk for having or developing a blood clot (Part A only)
    - Any leftover serum or plasma (components of blood) from the safety lab samples may be stored and used to assess exploratory safety biomarkers or unexpected safety findings
        - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
    - Study Drug Levels: Blood, urine, and feces (urine and feces collection for Part B, Dosing Sequence 1, Period 1 only, all samples collected for the entire study period) samples will also be used to measure the levels of study drug and study drug-related material (Part B only)
        - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for the following:
            - Metabolite identification
            - Metabolite profiling (Part A, Groups 2 and 4 – 7, and possibly optional groups 8 and 9, and Part B)
                - ✓ Metabolite profiling involves identifying and measuring specific metabolites that originate in the body
            - Evaluate safety aspects related to any concerns during or after the study
            - Check the laboratory test which measures the study drug
            - Other internal exploratory purposes
    - Pharmacodynamics: Blood samples will also be used to determine how your body responds to the study drug (Part A only)
        - BCAA
        - BCKA
        - Blood samples may also be used for the following:

        - Metabolite identification
        - Evaluate safety aspects related to any concerns during or after the study
        - Check the laboratory test which measures the study drug
        - Other internal exploratory purposes
    - Other: Urine samples may also be used to measure (Part A only):
        - Pyridoxic acid (PDA) (a metabolite of Vitamin B6)

      Blood samples may also be used to measure (Part A only):
        - PDA
        - 4β-hydroxycholesterol (a form of cholesterol)
        - Cholesterol
        - CP-I (breakdown product of substances forming red blood cells)
    - Retained Research Samples: Samples of your blood will be collected, stored, and used to learn more about the study drug
        - Biological substances in your samples, including your genes, may be studied
        - These samples may be kept by Pfizer for as long as the samples are useful for scientific research. This may be for many years without a specified time limit
- You will return to the CRU for a follow-up visit about 7 days after the last dose of study drug
- You will receive a follow-up phone call about 4 weeks after the last dose of study drug
- For safety reasons we may add procedures at any time during the study to check on your health status

Blood Draws

Blood samples will be taken by individual needlesticks, or by a catheter. A catheter is a small tube that is placed in a vein in your arm to take blood when required. Catheters are used when ordered by the study investigator or when required by the study plan. They are not used at the request of the participant.

There will be up to about 39 blood draws in Part A and about 41 in Part B of the study. The total amount of blood drawn during the study will be about 515 mL in Part A and about 250 mL in Part B. This is equal to about 17 ½ oz., or about a little more than 2 cups in Part A and a little more than 8 ¼ oz, or a little more than 1 cup in Part B. For comparison, the standard blood donation is about 16 oz. (2 cups), once in any 56-day period.

As with all studies with blood draws, rest and good eating habits are recommended.

Blood loss in this amount (Part A only) may lead to a low red blood cell count (anemia). Anemia **can** make you feel more tired than usual.

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug or procedure(s) may make you feel unwell or uncomfortable or could harm you. If you do not understand what any of the side effects described below mean, please let us know. The study investigator or study staff will explain them to you.

It is important that you report all side effects that you have as soon as they occur. This is regardless of whether or not you believe they are caused by the study drug or your participation in this study.

If you are not honest about any side effects that you have during the study, you may be harmed by staying in the study.

Study Drug Risks

As of August 23, 2023, there has been one study that has been completed where single doses of the study drug, or a matching placebo, have been given to people. In all, 20 people, who were healthy adults, participated in this completed study. Single doses from 10 mg to 1500 mg were given in this study. Most of the side effects were mild and the most common side effect reported was headache. However, two serious adverse events were noted in this study which have necessitated additional safety measures in this study as discussed below.

One serious adverse event (side effect) was reported during the follow-up period in 1 participant (out of 9 participants) in the first group of this completed, single dose study. This participant completed all 4 periods of the study and received single doses of the study drug in each of 3 study periods and a single dose of placebo in 1 period. There were at least 7 days between each dose. An adverse event of "seizure" was reported in this participant during the follow-up period, 7 days after a dose of placebo was given in Period 4 of the study. This participant required assessment in the Emergency Department for this adverse event but did not require hospitalization or any specific treatment. As of August 23, 2023, the Study Investigator could not exclude the possibility that the blinded study drug (study drug or placebo) may have contributed to this adverse event. This event was also reviewed by the Pfizer safety team and by a Pfizer Risk Management Committee. These 2 teams thought that the event was unlikely to be related to the blinded study drug because:

- The study drug is not thought to enter brain tissue
- There were several days between the last dose of study drug and the event

In addition, no seizures were seen in any of the rat or dog studies described below. Out of an abundance of caution, participants in this study will be monitored closely with serial physical exams directed at identifying any neurological signs or symptoms.

In the current multiple dose study, one serious adverse event was reported during the follow-up period in 1 participant (out of 10 participants) in the first dosing group. This participant completed 14 days of dosing and reported no symptoms during the dosing period and within 1 week of completing dosing, aside from mild heartburn 3 days after completing dosing. An adverse event of "venous thromboembolism" (blood clots in the leg and lungs) was reported during the follow-up period. This began as leg pain at least 7 days after the last dose of blinded study drug was given. The participant was hospitalized for treatment and evaluation and was discharged in stable condition on a blood thinner. As of the time of this reported incident, the Study Investigator could not exclude the possibility that the blinded study drug (the study drug or placebo) may have contributed to the adverse event. This event was also reviewed by the Pfizer Safety Team and by a Pfizer Risk Management Committee. These reviews concluded that the event was possibly related to the blinded study drug. No other participants in studies with the study drug have reported leg pain, shortness of breath, or blood clots. To minimize any risk to study participants, the following approaches will be taken:

- Potential participants who may be at elevated risk of blood clots (based on medical history or screening tests) will be excluded from participation
- Study participants will be monitored with physical exams targeted to detect signs of blood clots
- Study participants will undergo laboratory testing to monitor for evidence of clotting activity

There are no other drugs, either on the market or in clinical trials, that work in a similar way to the study drug. As a result, this summary is also based on information collected in animals.

In animal studies done before clinical trials, rats and dogs were dosed with the study drug for up to a month. Animal studies do not always predict the side effects that humans may experience. All noteworthy findings in these animal studies were seen at high doses. These doses are higher than the levels that you will be exposed to in this study.

At the highest dose of study drug given in a 2-week study in rats, one rat died and another was put down due to poor general condition and weight loss. The study drug levels at this dose in rats were 48 times higher than the highest exposure levels expected in humans. At the highest dose of study drug given in a 4-week study in dogs, 2 dogs were put down due to neurological side effects (tremors and balance problems). The study drug levels at this dose in dogs were 27 times higher than the highest exposure levels expected in humans.

In animal studies done after the ones mentioned above, lower repeat-doses were given to rats and dogs for up to 1 month. There were no deaths or adverse findings. Findings in these studies were considered not adverse due to limited severity or extent, lasted only a short time, or lacked an association with significant abnormalities seen under the microscope and included:

- Higher food consumption in rats
- Higher heart weights in rats
- Stomach discoloration in rats
- Microscopic changes in the pancreas in rats
- Changes in hematology and blood chemistry tests in rats
- Vomiting, increased saliva production, and changes to the feces in dogs

Following single doses of study drug in rats, the following were seen (these changes are not expected to pose a significant safety issue in humans):

- Changes in front limb strength and grip strength
- Small decreases in lung function measures which lasted only a short time

In a cardiovascular (heart) study in dogs, decreases in blood pressure were seen, but were not seen in a later similar study also in dogs.

There were no blood clots found in any of the animal studies.

The highest dose of study drug planned in this study is lower than the dose level at which no adverse events were seen in animals.

During this study, you may receive multiple doses of study drug or placebo in Part A, or single doses of study drug in Part B. This highest daily dose of the study drug that you will likely receive will not be greater than 1500 mg and/or will not result in study drug levels higher than the level at which no adverse events were seen in animals. However, based on the animal studies findings described above, study participants will be monitored closely. Repeat assessments to identify any similar abnormalities include:

- Physical exams, including neurological assessment and focused clinical exams to check for blood clots
- Blood pressure
- Heart rate
- Breathing rate
- ECG

- Blood tests

The study drug may make your skin more sensitive to the sun's rays. Skin problems linked to sun exposure could happen. Because of this, you will be asked to avoid exposure and protect yourself from the sun throughout the study through your last follow-up contact with the CRU. You will have to limit your sun exposure times as well as the area(s) exposed (for example, wear long pants and long sleeve shirts). You should avoid exposure to sun lamps. When outside in the sun you should wear sunglasses and put on protective sunscreen cream with a sun protection factor (SPF) of at least 50.

Until you know how the study drug will affect you, you should use caution by:

- Avoiding stairs
- Not driving a car
- Not swimming or bathing in a tub
- Not working with machinery or at heights

Ensure Plus® Risks (Part A only)

Common side effects include:

- Constipation
- Diarrhea
- Vomiting
- Nausea

Part B (Dosing sequence 1, Period 1 only)

Dietary Fiber Supplement Risks

The side effects of a fiber supplement include:

- Abdominal discomfort
- Bloating
- Gas
- Stomach cramping
- Mild diarrhea

Prune Juice Risks

The most common side effect from drinking prune juice is an increase in gas.

Stool Softener Risks

The side effects of a stool softener include:

- Gas
- Bloating
- Diarrhea
- Mild nausea

Milk of Magnesia Risks

The most common side effect of milk of magnesia is diarrhea.

Other Risks

Because the study drug is investigational, all of its side effects are not known. There may be rare and unknown side effects. These include reactions that may be life-threatening.

All drugs have a potential risk of an allergic reaction. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help right away (by calling 911 or immediately going to an emergency room) if you think you have any of the following symptoms:

- Trouble breathing
- Wheezing
- Difficulty swallowing
- Swelling of the face, mouth, lips, gums, tongue, or neck

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations (racing heart)
- Chest discomfort/tightness
- Muscle pains/stiffness

At times, the following may also be symptoms of an allergic reaction:

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain

If a significant side effect occurs, the following may be done:

- Tests or treatment may be given as needed for your safety
- Depending on how severe your symptoms are, you may be seen by outside medical providers or a hospital. This would be for further evaluation and/or treatment
- The study investigator may notify your emergency contact as appropriate in the event of an emergency while you are taking part in the study

Additional Risks or Discomforts

Testing of DNA and/or RNA (deoxyribonucleic acid and/or ribonucleic acid)

Genes are pieces of DNA that give coded instructions for the body. Parts of the code are passed down from parents to their children.

The genes in your samples may be studied. This may include analyzing all of your genetic information. This is called "whole genome sequencing." While collection of genetic information does not expose you to physical risk, collection of such information may result in a loss of your privacy if your genetic information is lost or stolen.

There is a very small chance that your genetic information could be misused by people not involved with the research, including to discriminate against you. However, steps are in place to prevent a particular result from being linked to you and to prevent unauthorized people from even knowing genetic research was done.

U.S. federal law prohibits discrimination in health insurance coverage and employment based on a person's genetic data. However, U.S. federal law does not protect against discrimination when you are applying for:

- Life insurance
- Long term care insurance
- Disability insurance

You should talk to your physician or genetic counselor about the potential for genetic discrimination.

The results of tests on your sample(s) will not be given to:

- You
- The study investigator
- Any insurance company
- Your employer
- Your family
- Any physician who treats you

Blood Samples and IV Catheters (if used)

Possible side effects of having your blood drawn or an IV catheter inserted include:

- Bleeding at the site of the needle puncture
- Bruising
- Feeling faint
- Rarely, infection or blood clot
- Redness of the vein
- Inflammation of the vein
- Swelling
- Pain
- Nerve damage
- Vein irritation from the fluid or medication being given
- Local swelling due to IV fluid accidentally entering the tissue rather than the vein
- Scarring

If you feel faint, tell one of the study staff immediately.

COVID-19 Testing

Collection of a swab sample may cause:

- Discomfort
- Sneezing
- Your eyes to water
- Gagging
- Possible nosebleed

There is a risk of COVID-19 infection when you are in close contact with study staff or other study participants during the screening process and during the study. However, safety procedures will be followed during screening and the study to minimize the risk of COVID-19 transmission.

If you test positive for COVID-19 while on study, you may not be able to continue in the study. If you have a positive result, it may be reported to the Connecticut State Department of Health and your local department of health. If you have any questions about what information may be reported, please ask the study investigator or study staff.

ECG and Continuous Heart Monitoring (Part A only)

Possible side effects from having an ECG and continuous heart monitoring include:

- Irritation or rash from the adhesive on the patches

A rash may result in a long-lasting discoloration of your skin. If it is necessary to shave the area where the patches need to be, irritation from shaving may occur.

Fasting

Fasting could cause symptoms such as:

- Dizziness
- Headache
- Stomach discomfort
- Fainting
- Hypoglycemia (low blood sugar)

Other

The length of time that you may be confined to the CRU may make you feel uncomfortable.

Use of Birth Control

Females unable to have children

Women in this study should not be able to get pregnant or be breastfeeding. You may take part in this study provided that you meet one of the following:

- Have had your uterus removed (documented)

- Have had both fallopian tubes removed (documented)
- Have had both ovaries removed (documented)
- Have not had a period for at least 12 months in a row with no other medical cause. You must have a blood hormone level confirming that you cannot get pregnant

Females permanently unable to have children due to a medical cause not listed above may be allowed to participate in the study at the discretion of the study investigator.

Males

You must agree to the following during the study and for at least 28 days after the last dose of study drug:

- Refrain from donating sperm

PLUS either

- Be abstinent from heterosexual intercourse as your preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent

OR

Must agree to use birth control/barrier as detailed below:

- Agree to use a male condom and should also be advised of the benefit for a female partner to use a highly effective method of birth control as a condom may break or leak when having sexual intercourse with a female able to have children who is not currently pregnant

- In addition to male condom use, a highly effective method of birth control may be considered in female partners able to have children of male participants

Highly effective methods of birth control include:

- Implantable progestogen-only hormone birth control
- Intrauterine device (IUD)
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has a vasectomy (absence of sperm confirmed)
- Hormonal birth control
- Sexual abstinence – defined as refraining from heterosexual intercourse and is the preferred and usual lifestyle of the participant

Pregnancy-Related Risks

The effects of the study drug on the following are not known and may involve unforeseeable risks:

- Sperm
- Pregnancy
- Unborn child
- Breastfeeding child

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

You cannot participate in this study if:

- You are a man whose female partner is currently pregnant or planning to become pregnant

If you want to stop your required birth control during the study, you should tell the study investigator **immediately**. You will be taken out of the study if you stop using birth control.

Pregnancy Follow-Up

If you or your partner becomes pregnant during the study or within 28 days after your last dose of study drug, please:

- Tell the study investigator **right away**
- Tell the health care provider(s) taking care of your partner during the pregnancy that you took part in this study

The study investigator will ask if you/your partner or your/her health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. This information will be collected for safety monitoring follow-up.

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and diet and activity restrictions (details listed later in this document)
- You must not have any significant medical or psychiatric condition, as determined by the study investigator, that may put your safety at risk or could have an effect on the study results
- You must not have evidence of a prothrombic state (condition associated with blood clots) as demonstrated by any of the following (Part A only):
    - History of DVT, pulmonary embolism (blood clot in the lungs), arterial thrombosis (blood clot in an artery)
    - Known genetic (inherited from a parent) predisposition based on medical history
        - The Study Investigator will review these conditions with you
    - Any abnormalities in clinical lab tests at screening associated with coagulation system abnormalities
- Optional Japanese participants must have 4 Japanese biological grandparents who were born in Japan
- You must not have a history of photosensitivity or phototoxicity (skin reactions in response to light)
- You may be asked to provide documentation of your childbearing status

- You must not take any medications (including over-the-counter medications, such as medications for cold or allergies, antacids, herbal supplements, minerals, or vitamins) within 7 days before the first dose or at any time during the study
    - You must not take hormone replacement therapy (HRT) within 28 days before the first dose or at any time during the study
    - Before taking any drugs other than the study drugs, you must call the CRU for approval. It must first be approved by the study investigator
    - You must tell the study staff about any drugs taken during the study
- You must not have taken any medications or substances that are moderate or strong CYP3A4 (a gene that alters enzyme activity in the body) inducers or time-dependent inhibitors within 14 days plus 5 half-lives (which is drug dependent) of the first dose or during the study
    - The study investigator or study staff will review a list of these medications and substances with you
- You must not have been vaccinated with a COVID-19 vaccine within 7 days before screening or within 7 days before any study visit in which a safety lab is scheduled
- You must not take any investigational product (drug or vaccine) within 30 days before the first dose of this study
- You must not have had previous exposure to the study drug
- You must not have donated blood for at least 60 days before dosing. Plasma (a component of blood) donation may be allowed
    - You cannot donate any blood or blood products at any time during this study. Donation is not allowed for at least 4 weeks after your last blood draw
- You must not have a history of excessive alcohol use or binge drinking and/or other illicit drug use within 6 months before screening
    - Binge drinking is defined as a pattern of 5 (male) or 4 (female) or more alcoholic drinks in about 2 hours
    - You should not drink more than 14 alcoholic drinks a week
    - A drink is defined as 8 oz. (1 cup) of beer, 3 oz. (6 tablespoons) of wine, or 1 oz. (2 tablespoons) of hard liquor
- You must not be using/taking any drugs of abuse (such as marijuana, cocaine, opioids, etc.). Urine tests will be done to check for such drugs.
    - If a test is positive, you will not be allowed in the study
    - Urine collection may be monitored by a staff member of the same sex
    - You have the right to refuse to be monitored, but may be disqualified from the study
    - While in this study, please do not eat anything that contains poppy seeds. They may cause a positive drug test
- You must not use tobacco or nicotine-containing products in excess of the equivalent of 5 cigarettes or 2 chews of tobacco per day
- You must not use tobacco- or nicotine-containing products for 24 hours before the first dose and while confined to the CRU
- Please let us know if you or a relative are a staff member of Pfizer. If so, you may not take part in this study if you or your relative are supervised by the study investigator or are directly involved with the study

Activity Restrictions

- You will need to stay in the CRU for 18 days (Part A) starting with check-in

- You will need to stay in the CRU for 23 (Dosing Sequence 1) or 18 (Dosing Sequence 2) days (Part B) starting with check-in
    - You may need to stay in the CRU longer if you experience a longer study drug effect. This is for safety reasons
    - The study investigator or study staff will decide when it is safe for you to leave the CRU
- You must not do any strenuous exercise for at least 48 hours before each blood draw for safety labs. Examples of this include heavy lifting, weight training, or aerobics
    - Walking at a normal pace is allowed
- You may be asked to wear a device (similar to a wristwatch) that can be used to alert study staff in case of an emergency
- You will be confined to the procedure room for the first 4 hours after morning dosing on Day 7, 10 and 14 (Part A only) during continuous cardiac monitoring, except to use the bathroom
- You cannot lie down for 4 hours after dosing on Days 1, 7 and 14 (Part A) or Day 1 of each period (Part B), unless needed for study procedures
- You are advised to avoid direct sunlight or any high intensity UV light exposure from your first admission to the CRU through your last follow-up contact with the CRU
    - You should apply sunscreen with a sun protection factor (SPF) of greater than or equal to 50 and wear eye-protective sunglasses

Diet Restrictions

- You must not eat or drink anything except water for at least 4 hours before each safety laboratory test and 8 hours before the collection of pre-dose study drug levels and PD biomarker samples (Part A)
- You must not eat or drink anything except water for at least 10 hours before dosing or eating a high-fat breakfast (Part B)
- You must not eat or drink anything except water for at least 10 hours before morning dosing on Day 1, 7, and 14 if dosing under fasting conditions (Part A)
    - Except for 1 hour before and 1 hour after morning dosing you may drink water freely
- You must not drink red wine for 7 days before the first dose. Red wine is not allowed through the collection of the last blood sample for study drug
- You must not eat or drink anything with alcohol for 24 hours (or as stated above for red wine) before check-in. Alcohol is not allowed through the collection of the last blood sample for study drug in each period
    - Study staff may check your breath for alcohol. If alcohol is found, you will not be allowed in the study
- You must not eat or drink anything with caffeine for 24 hours before dosing. Caffeine is not allowed through the collection of the last blood sample for study drug in each period
    - Caffeine can be found in different foods and drinks. Some examples include chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything that has grapefruit or grapefruit-related citrus fruits for 7 days before the first dose. These are not allowed through collection of the last blood sample for study drug
    - Examples of citrus fruits that are not allowed are Seville oranges and pomelos
    - Fruit juices and smoothies may also contain grapefruit or these citrus fruits
- Breakfast or Ensure Plus® (or similar protein rich meal) will be provided about 30 or 20 minutes, respectively, before morning dosing
    - No food or drink, except water, will be allowed for at least 4 hours after dosing
- Lunch will be provided about 4 hours after dosing and at the same time on Day-1, if applicable
- Dinner will be provided about 10 hours after dosing and at the same time on Day-1, if applicable

- An evening snack is allowed
    - When dosing twice a day (Part A only), the snack will be given about 20 minutes before dosing and should be completely eaten within 10 minutes
- You will be given the same meals on Day 1, 7 (same breakfast only), 14, and -1, if applicable (Part A)
- Meals (breakfast, lunch, dinner, and evening snacks) will be provided at appropriate times on all other study days
- You are encouraged to eat your entire meals on Day -1, 1, 7, and 14, and evening snacks on Day -2, -1 and 13 (Part A)

Possible Benefits of the Study

This study is for research purposes only. There may be no direct benefit to you from taking part. However, information learned from this study may benefit other people in the future.

Alternatives to Participating in this Study

This study is for research purposes only. Your alternative is to not take part in the study.

Confidentiality

This section describes how we will collect, use, and share your personal information.

What personal information may we collect about you during this study?

The study staff will collect information about you. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, date of birth, and Social Security Number
- **Personal information** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as race, ethnicity, sexuality, substance use disorders, mental health disorders, diagnoses and treatment, and HIV status
- **Data from testing and analysis of biological samples** (such as blood or urine). This may also include genetic information
- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet. This information may include:
    - The length of time it takes you to complete the consent process
    - The number of times you scroll between pages or click hyperlinked items
    - Your electronic signature

Who will use my personal information, how will they use it, and where will it be stored?

Any personal information collected during this study will be stored by the study staff at the CRU. The study staff must keep your personal information confidential.

Your personal information will be accessed by:

- The study investigator and other study staff members
- Pfizer and its representatives (including its affiliated companies)

- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. FDA and authorities in other countries)
- Advarra Institutional Review Board (IRB), the IRB that reviewed this study and any other committees responsible for overseeing the research

The individuals and groups listed above will use your personal information to conduct this study, and to comply with legal or regulatory requirements, including to:

- Determine if you are eligible for this study
- Provide you with reimbursement, as allowed by the study, for your time, effort, and certain expenses related to your participation
- Verify that the study is conducted correctly and that study data are accurate
- Answer questions from IRB(s) or government or regulatory agencies
- Assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process
- Contact you during and after the study (if necessary)
- Follow-up on your health status, including using publicly available sources (for example, public databases or the internet) should the study staff be unable to contact you using information held on file
- Protect your vital interests such as providing information to an emergency department of a hospital if you are being treated
- Answer your data protection requests (if any)

If you provide someone else's personal information, you should make them aware that you have provided the information to us. Examples of this information include:

- Emergency contact information
- Details of family medical history

We will only use such information in keeping with this informed consent and applicable law.

Text Messages

If you agree, the study staff, or a company working on behalf of Pfizer, may send text messages using an automated system to remind you of:

- Upcoming study appointments
- Other study-related information
    - Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier. Please contact your wireless phone provider to ask about the details of your plan
    - The contact information you have provided will be used for the sole purpose of communicating with you about the study
    - The text messages received through this program may appear on your mobile phone screen as soon as they are received. This may happen even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received
    - To discontinue receiving text messages, please contact the Pfizer New Haven CRU at 800-254-6398

You will be asked to make your choice at the end of this document.

What happens to my personal information that is sent outside the CRU?

Before the study staff transfers your personal information outside the CRU, the study staff will:

- Replace your name with a unique code
- Remove information that directly identifies you

This is called "**Coded Information**." The link between the code and your personal information will be kept confidential by the study staff.

Your Coded Information will be used by the following:

- Pfizer and its representatives (including its affiliated companies)
- People and/or organizations providing services to or collaborating with Pfizer
- Any organization that obtains all or part of Pfizer's business or the rights to the product under study
- Other researchers
- Advarra IRB
- Government or regulatory authorities

The above parties may use your coded information for the following purposes:

- **Conducting the study**, including:
    - Examining your response to the study drug
    - Understanding the study and the study results and learning more about heart failure
    - Assessing the safety of the study drug
- **Complying with legal and regulatory duties** such as:
    - Ensuring the study is conducted according to good clinical practice
    - Making required disclosures to IRB(s), or government or regulatory authorities
    - Seeking approval from government or regulatory authorities to market the study drug
        - It is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research
    - Sharing study data with other researchers not affiliated with the study staff or Pfizer. This includes through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers
- **Publishing summaries of the study results:**
    - In medical journals
    - On the internet
    - At educational meetings of other researchers

  You will not be directly identified in any publication or report of the study. But some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you be made available to other researchers for further research projects.
- **Improving the quality, design, and safety** of this study and other research studies

How are my biological samples handled?

If biological samples are taken during the study, those samples will be handled in the same way as your Coded Information. All samples will be treated as required by law.

Can my coded information and biological samples be used for other research?

Yes. Pfizer may use your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of this study, to support and advance other scientific research projects, including improving the quality, design, and safety of other research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products, and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information, biological samples, image and/or audio/video recordings used in any future research and may include:

- Limiting access to individuals bound by duties of confidentiality
- Taking steps to minimize the risk that you could be re-identified
- Obtaining approval of ethical review boards

Furthermore, if your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, have identifiers removed such that they can no longer be readily identified with you, they may be used for future research purposes.

Study-Related Injuries

You will also receive a card with information about this study. This information includes:

- The name or number of the study
- The CRU 24-hour phone number

You should keep this card with you in case you have a medical emergency. You can give this card to any healthcare provider if they need more information about the research study to provide the best treatment for you.

If you experience a research injury, the CRU will arrange for medical treatment at no cost to you. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by being in this study. There are no plans to offer you payment for such things as:

- Lost wages
- Expenses other than medical care
- Pain and suffering

To help avoid injury, it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.
You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. A 24-hour answering service is available.

If you are treated for a research injury that is paid for by Pfizer, Pfizer or its representative will collect your:

- Medicare Health Insurance Claim Number or,
- Social Security Number

This is to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services (CMS). This is in keeping with CMS reporting requirements. Pfizer will not use this information for any other purpose.

Legal Rights

You will not lose any of your legal rights by signing and dating this consent document.

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;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedure;

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

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

An institutional review board (IRB) is an independent committee established to help protect the rights of research 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: Pro00070264.

Link to Additional Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Payment for Taking Part in the Study

The amount of payment is based on a number of things including the length of the study. Travel pay for this study has been included in the payment.

You may be eligible for a travel and hotel bonus payment:

- $0.20/mile per one-way trip to or from the CRU based on your home address
- For participants traveling long distances, a 1-night hotel stipend ($150.00) for the night prior to your visit(s), if needed

Additional travel services may be arranged on your behalf at no cost to you.

All payments will be in U.S. dollars. Compensation may be provided on a loadable debit card or by paper check. Pfizer New Haven CRU reserves the right to determine method of payment.

U.S. Citizens: Payments may be considered taxable income. If you receive $600.00 or more in taxable payments within a calendar year, your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1099). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 24% and receive a tax form (1099). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

Non-U.S. Citizens: Payments may be considered taxable income. Your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1042-S). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 30% and receive a tax form (1042-S). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

If at any time you test positive for drugs of abuse, you will not be paid for your visit. Further, if you test positive for drugs of abuse:

- You will not be allowed to be in this study
- You may not be allowed to be in any future studies

Screening Payments

The screening payment is listed below. You will receive this payment within 2 weeks of screening. If you leave the screening early, you will not be paid.

Screening Visit at CRU	$175.00

Additional payments are made if we ask you to return to the CRU to repeat any screening tests ($100.00 per visit).

Study Payments

The payment for completing the entire study is listed below. Please be aware that:

- If you do not follow instructions (including those listed in the New Haven CRU House Rules), if you are late for blood draws, or if you miss procedures, your payment may be reduced. You will be paid a prorated amount based on the extent of your participation if:
    - You are not able to complete the study
    - You choose to leave the study
    - You are withdrawn from the study early by the study investigator for non-safety-related issues
    - The study is stopped early
    - You are qualified but not chosen to participate
- You will not be given the study completion bonus if you drop out of the study early
- Partial payments are planned during the study. Details will be provided at screening
- A final payment will be provided to you within 2 weeks of finishing the study
- Pfizer may use information resulting from the study or samples collected in the study to develop products or processes. Pfizer may make a profit from these. There are no plans to pay you or provide you with any products developed from this research. Pfizer will own all products or processes that are developed using information or samples from the study

The decision to admit you into the study is based upon results of pre-study requirements. No one is guaranteed a place in the study until the first dose is complete. Enough numbers of participants will be brought in to be sure we fill the study.

STUDY PARTICIPANTS – PART A			
Type of Activity	**Payment per Activity**	**Total Number (Days/Weeks)**	**Total**
Overnight Stay	$240.00	18	$4,320.00
Duration of Follow-Up Period (Discharge to Follow-Up Call)	$15.00	26	$390.00
Follow-Up Visit to CRU	$250.00	1	$250.00
Follow Up Phone Call	$100.00	1	$100.00
Completion Bonus	$1,350.00		$1,350.00
Total Payment Part A	$6,410.00		

STUDY PARTICIPANTS – PART B (DOSING SEQUENCE 1)			
Type of Activity	**Payment per Activity**	**Total Number (Days/Weeks)**	**Total**
Overnight Stay	$245.00	23	$5,635.00
Duration of Follow-Up Period (Discharge to Follow-Up Call)	$15.00	26	$390.00
Follow-Up Visit to CRU	$250.00	1	$250.00
Follow Up Phone Call	$100.00	1	$100.00
Completion Bonus	$1,610.00		$1,610.00
Total Payment Part B	$7,985.00		

STUDY PARTICIPANTS – PART B (DOSING SEQUENCE 2)			
Type of Activity	**Payment per Activity**	**Total Number (Days/Weeks)**	**Total**
Overnight Stay	$245.00	18	$4,410.00
Duration of Follow-Up Period (Discharge to Follow-Up Call)	$15.00	26	$390.00
Follow-Up Visit to CRU	$250.00	1	$250.00
Follow Up Phone Call	$100.00	1	$100.00
Completion Bonus	$1,260.00		$1,260.00
Total Payment Part B	$6,410.00		

BACK-UP PARTICIPANTS	
Type of Activity	**Payment per Activity**
Overnight Stay	$300.00
Daytime Stay	$190.00

Additional payments are made if we ask you to return to the CRU or to outside medical providers for additional tests ($250.00 per visit). During times that you need to stay in the CRU, you will not be paid more for repeat or added tests.

Costs for Study Participants

The study drug, study-related procedures, and study visits will be provided at no cost to you.

Your Decision to be in the Study

Taking part in this study is voluntary. You cannot be forced to be in this study. You may leave the study at any time without penalty or loss of any benefits. Your future medical care will not be affected. The study investigator, Pfizer Inc, or the FDA may take you out of the study without your permission at any time for the following reasons:

- You do not follow the instructions of the study investigator

- We find out you should not be in the study
- The study is stopped
- The study becomes harmful to your health
- You do not follow the New Haven CRU House Rules

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the CRU for a final visit. You may have some end of study tests at this visit. This is to make sure it is safe for you to leave the study. The data collected to the point of your withdrawal remains part of the study database and may not be removed.

If you are withdrawn from the study, or decide to stop the study, you can ask that any unused samples that were collected be destroyed. If you would like to have this done, please contact the study investigator. However, your samples may not be able to be destroyed because:

- They may no longer be traceable to you
- They may have already been used
- They may have been given to a third party

New Findings

If there is new information about the safety of the study drug or changes in the study tests, we will tell you in a timely manner. You can then decide if you still want to be in the study.

AGREEMENT TO BE IN THE STUDY **PIMS # _____**

This consent document 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 document, ask one of the study staff.

By checking each of the following, you are agreeing that the statements below are true:		Please Check
A.	This consent document is written in a language I understand	
B.	I understand the information in this consent document	
C.	I have been given enough time to ask questions and talk about the study	
D.	All of my questions have been answered completely	
E.	I have received enough information about the study	
F.	I agree that I was not pressured by the study investigator or the study staff to be in this study	
G.	I know that I can leave the study at any time without giving a reason and without affecting my health care	
H.	I know that my health records from this study may be reviewed by Pfizer Inc and by government officials	
I.	I know that I cannot be in another study while I am in this study	
J.	I have received the HIV, Hepatitis A, B, and C pamphlets and reviewed the information in them	

IF YOU DID NOT CHECK THE BOX NEXT 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 DOCUMENT

Text Messages:
Please check the box next to your choice.

☐ Yes, I agree that the study staff may send me text messages as described in the Confidentiality section

☐ No, I do NOT agree that the study staff may send me text messages as described in the Confidentiality section

- You will get fa copy of this signed and dated ICD for your records
- You agree to participate in this study
- It is your responsibility to tell the study investigator about all changes in your physical or mental health during the study

Printed Name of Adult Study Participant (Name as appears on U.S./State Government-Issued ID)

Signature of Adult Study Participant Date

Printed Name or Initials of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent Date