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FEBRUARY 8, 2021

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Pfizer Inc
NUMBER AND NAME OF STUDY:	C4671001; "A PHASE 1, RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO CONTROLLED, SINGLE- AND MULTIPLE-DOSE ESCALATION STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF PF-07321332 IN HEALTHY ADULT PARTICIPANTS"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY INVESTIGATOR):	Sylvester Pawlak, APRN
TELEPHONE NUMBER 24 HOURS:	203-401-0300

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-07321332 will be referred to as the "study drug" in the rest of this consent document.

The purposes of this study are:

Part 1:

- To see how a new drug under study is tolerated as the dose is increased, alone or with ritonavir, if there are significant side effects, and how people feel after taking it
  - Ritonavir would act as a booster by increasing the amount of study drug in your blood
- To measure how much of the study drug and its metabolites are in your blood after you take a single dose alone or with ritonavir
  - A metabolite is a by-product of a drug as the body processes it
  - In 1 group, the amount of study drug and metabolites in your urine and feces will also be measured
- To compare the amount of study drug in your blood after you take different forms of the study drug (liquid or tablet)
- To find out the amount of study drug in your blood after you take a single dose of the study drug as a tablet with and without food

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Part 2:

- To see how a new drug under study is tolerated after multiple doses (more than 1) as the dose is increased, alone or with ritonavir, if there are significant side effects, and how people feel after taking it
- To measure how much of the study drug is in your blood and urine after you take multiple doses alone or with ritonavir

Part 3 (if done):

- To compare the amount of study drug in your blood after you take different forms of the study drug (liquid or tablet)
- To find out the amount of study drug in your blood after you take a single dose of the study drug as a tablet with and without food
- To see how a new drug under study is tolerated, in liquid and tablet forms, if there are significant side effects, and how people feel after taking it
- To evaluate the taste of the liquid form

This will be the first time that the study drug will be given to healthy adult participants or in combination with any other drugs. The effects (both good and bad) of the study drug in people are therefore not known.

The study drug is an investigational drug being studied to treat people with SARS-CoV-2 (COVID-19). In December 2019, COVID-19 was identified as a new, potentially fatal, respiratory infection caused by the novel coronavirus, SARS-CoV-2. The World Health Organization (WHO) declared COVID-19 a Public Health Emergency of International Concern on 20 January 2020 and further characterized the disease outbreak as a pandemic on 11 March 2020. COVID-19 manifests as a wide range of illnesses, from asymptomatic infection to severe pneumonia, acute respiratory distress syndrome (ARDS) and death. "Investigational" means that the drug has not been approved by the United States (U.S.) Food and Drug Administration (FDA).

Study drug or placebo will be given as oral (by mouth) liquid, which you will drink, or tablet, which you will swallow whole. 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.

Ritonavir may also be given in this study. Ritonavir is similar to Norvir®. Ritonavir is an approved marketed antiviral medication. It is used to treat people with human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS). The use of ritonavir in this research study is an interacting agent to boost the blood level of study drug. The treatment doses of ritonavir are generally higher and given for a longer time than what may be given in this study.

In this consent document, you may see the terms "medication", "treatment", and "treatment period". These terms often are used in research studies. When you see these terms in this consent document, it does not mean that you will be receiving medical care for any condition.

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ABOUT THE STUDY

The study has up to 3 parts (Part 1, Part 2, and optional Part 3).

Number of Study Participants

This study is being done at about 2 different study sites in 2 countries. There will be up to 60 people in the study, 12 participants in Part 1, up to 30 participants in Part 2 (including 6 Japanese participants if the optional Japanese group is conducted) and a maximum of 18 participants in Part 3 (if done).

Length of Study for Participants

You will be in this study for about 58 days in Part 1, about 46 days in Part 2, and about 41 days in Part 3. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

Part 1:

- 2 to 4 dosing periods during 1 continuous admission
- 11 to 25 overnight stays at the Clinical Research Unit (CRU). You will not be able to leave the CRU during that time
- 1 follow-up phone call about 4 weeks after the last dose of study drug

There will be at least 5 days between each dose.

Part 2:

- 1 dosing period during 1 continuous admission, receiving multiple doses every day for 10 days in a row
- 12 overnight stays at the CRU. You will not be able to leave the CRU during that time
- 1 follow-up phone call about 4 weeks after the last dose of study drug

Part 3 (if done):

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

There will be at least 2 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. 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.

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Dosing Plan

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

Part 1 (single, increasing dose)

Two groups of participants are planned for this part of the study. There will be up to 6 participants in each of these groups.

The dosing is planned as follows:

		Dosing Periods			
Group	Number of Participants	Period 1	Period 2	Period 3*	Period 4*
1	2	A	C	E	TBD**
	2	A	C	E	TBD**
	2	A	C	E	TBD**
2	2	B	D	F	TBD**
	2	B	D	F	TBD**
	2	B	D	F	TBD**

*Dosing Periods 3 and 4 may not be needed
** To be determined

Treatment A: 150 mg study drug or placebo
Treatment B: 500 mg study drug or placebo
Treatment C: 1500 mg study drug or placebo
Treatment D: 3000 mg study drug or placebo
Treatment E: 150 mg study drug or placebo and 100 mg of ritonavir given 12 hours before study drug and 2 times a day on Day 1
Treatment F: 300 mg of study drug or placebo and 100 mg of ritonavir given 12 hours before study drug and 2 times a day on Day 1

The dose will increase only if it is believed to be safe. How well the study drug is tolerated and blood test results will be reviewed to help us to decide if it is safe.

Doses may also be divided differently, repeated, increased, or decreased based on study drug safety or blood levels.

Participants will receive up to 2 single doses of study drug and 2 doses of placebo, or 3 single doses of study drug and 1 dose of placebo, given as an oral suspension (liquid) or tablet. The order in which you receive these doses will be randomly assigned (like the flip of a coin). You have about a 1 in 3 chance of receiving placebo during any dosing period. Ritonavir (if used) will be a tablet. When dosed with ritonavir (if used), ritonavir will be given 3 times: 12 hours before the morning dose on Day 1, then at the same time as the study drug or placebo on Day 1, and then 12 hours after the study drug or placebo.

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Both you and the study staff will not know which of the above you are receiving. In case of a medical emergency, the study investigator can find out what you have received.

Fasted State:

- You will fast overnight (nothing to eat or drink except water) for at least 10 hours before dosing. You will not receive breakfast.

Fed State:

- You will be served breakfast about 30 minutes before dosing. Breakfast should be completely eaten within 20 minutes. Dosing will follow within 10 minutes of completing breakfast. Breakfast may be a standard or high-fat meal.
  - High-fat breakfast: An example is 2 eggs fried in butter, 2 strips of pork 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 in 20 minutes
  - If you agree to be in this study, you are agreeing to eat all the food listed in this menu

<u>Part 2 (multiple, increasing dose)</u>

Up to 5 groups are planned for this part of the study including 2 optional groups, and 1 optional Japanese group. There will be up to 6 participants in each of these groups.

Part 2 will start after the same or higher blood levels of study drug during a 24-hour period is found to be safe and well tolerated in Part 1 of the study.

The study drug or placebo will be administered either 2 times a day (every 12 hours) or 3 times a day (every 8 hours) for 10 days in a row. If needed, ritonavir 100 mg may be given every 12 hours at the same time as the study drug or placebo. The planned starting dose is 500 mg, the highest dose planned is 3000 mg.

Study drug or placebo will be given as an oral suspension (liquid) or tablet. It will be randomly assigned (like the flip of a coin) who receives either the study drug or placebo. You have about a 1 in 3 chance of receiving placebo. Ritonavir (if given) will be a tablet.

The planned treatments are:

Treatment A: 500 mg of study drug or placebo 3 times a day for 10 days

Treatment B: 1000 mg of study drug or placebo 3 times a day for 10 days

Treatment C: 150 mg of study drug or placebo with 100 mg of ritonavir 2 times a day for 10 days. On Day 10 the evening dose will be ritonavir alone.

Treatment D: 300 mg of study drug or placebo with 100 mg ritonavir 2 times a day for 10 days. On Day 10 the evening dose will be ritonavir alone.

The doses will increase only if it is believed to be safe. How well the study drug is tolerated, and blood tests will help us to decide if it is safe.

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Doses may also be divided differently, repeated, increased, or decreased based on study drug safety or blood levels.

Fasted State:

- You will fast overnight (nothing to eat or drink except water) for at least 7 hours before dosing for the morning dose and at least 2 hours before and after afternoon or evening doses.

Fed State:

- Morning dose: Following an overnight fast of at least 7 hours, you will be served breakfast about 30 minutes before dosing. Breakfast should be completely eaten within 20 minutes. Dosing will follow within 10 minutes of completing breakfast.
- Afternoon and/or evening dose:
    - A snack will be provided. The snack should be completely eaten within 10 minutes. The afternoon/evening dosing will follow within 10 minutes of completing the snack.

Both you and the study staff will not know which of the above you are receiving. In case of a medical emergency, the study investigator can find out what you have received.

Part 3 (Food Effect)

One group of up to 18 participants is planned. This group is optional.

The planned dose and number of participants will be determined based on the results of Part 1 and Part 2 of the study, but the selected dose will be the dose that has already been deemed safe in Part 1.

	Dosing Periods		
Treatment Sequence	Period 1	Period 2	Period 3
1	A	B	C
2	B	C	A
3	C	A	B

Treatment A: Study drug liquid formulation in fasted state
Treatment B: Study drug tablet formulation in fasted state
Treatment C: Study drug tablet formulation in fed state

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

On Day 1 of each period, you will receive a single oral dose of study drug.

- Fasted state: You will fast overnight (nothing to eat or drink except water) for at least 10 hours before dosing. You will not receive breakfast.
- Fed state: You will be served breakfast about 30 minutes before dosing. Breakfast should be completely eaten within 20 minutes. Dosing will follow within 10 minutes of completing breakfast. Breakfast may be a standard or high-fat meal.
    - High-fat breakfast: An example is 2 eggs fried in butter, 2 strips of pork bacon, 2 slices of toast with butter, 4 oz. of hash brown potatoes, and 8 oz. of whole milk

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- All of the breakfast should be eaten in 20 minutes
- If you agree to be in this study, you are agreeing to eat all the food listed in this menu

Part 1, Part 2, & Part 3

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

Liquid doses will be given with a total of about 8 oz. of liquid (includes the volume of the suspension and water). Tablet doses will be given with about 8 oz. of water. Tablet doses must be swallowed whole. Liquid doses must be completely swallowed. We will check your mouth after each dose of study drug or placebo and/or ritonavir to make sure doses have been swallowed.

Part 1 & Part 2

You may be offered a mint or candy to help cover up the taste of the study drug. This does not apply to Part 3 of the study.

This is a research study. The study drug(s) 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 and sign this consent document.

Screening

After you sign 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
- 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
- The proper use of birth control will be reviewed
- Height and weight will be measured
- Vital signs (blood pressure, heart rate, oral temperature, and breathing rate) will be measured
- Electrocardiograms (ECGs) will be collected. ECGs measure the electrical activity of the heart
- Safety lab tests will be done from blood and urine samples. This includes:
  - Blood tests for HIV, hepatitis B, and hepatitis C
  - Urine to test for drugs of abuse (illegal and prescription)
  - Females able to have children will have a blood pregnancy test

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  - 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
- All participants will be swabbed for COVID-19 at each visit to the CRU
  - Staff may be wearing masks, face shields, respirator hoods, gowns, and gloves
    - You will be provided a mask, and are required to wear it at all times
    - You will be tested for COVID-19 by collection of a swab sample
- The study investigator may decide to do an alcohol breath test
- Physical exam. This may be done at screening or when you check-in for the study
- 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 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 exam
- The use of proper birth control will be confirmed/reviewed
- Vital signs will be measured. Your oral temperature will also be measured
- You will be swabbed for COVID-19
- 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
- **Part 1 only:** Continuous heart monitoring will be done for at least 8 hours after dosing. There will also be a period of at least 2 hours 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

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  - 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
- **Part 3 only:** A taste questionnaire will be completed at various times (4 times in total)
- The study investigator may decide to do an alcohol breath test at any time
- 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 samples for pregnancy testing (females able to have children). Pregnancy tests may be performed at the discretion of the study investigator in all females
  - Any leftover blood and urine from the safety lab samples may be stored and used to assess exploratory safety biomarkers or unexpected safety findings. Biomarkers are natural substances in your body that can be used to show how your body works.
    - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
  - Banked Biospecimen: A sample of your blood will be collected and sent to Pfizer's biobank. Pfizer calls this sample a "Banked Biospecimen"
    - This sample will be used to study biological substances in your sample, including your genes. This will help us learn more about the study drug
    - This sample may be kept by Pfizer in a facility approved by Pfizer as long as the sample is useful for scientific research. This may be for many years (no time limit)
  - Study Drug Levels: Blood samples will be collected to measure the levels of study drug in your blood. These samples may also be used for exploration of metabolites or other internal exploratory purposes.
    - **Part 2:** Some of the blood samples may be collected using an investigational automated blood draw device
    - **Part 2:** Urine samples will also be used to measure study drug levels. These samples may also be used for metabolite profiling if needed.
  - Metabolite Profiling:
    - **Part 1 (Group 1 in Period 2)** – Blood, urine, and feces samples will be collected to measure metabolites and drug-related material
      - Prior to dosing on Day 1, urine sample will be collected. All of your urine will be collected starting on Day 1 from 0-24H, 24-48H, 48-72H, 72-96H, and 96-120H
      - If possible, a feces sample will be collected within 48 hours prior to dosing. All of your feces will be collected from the time of dosing on Day 1 through 120 hours post dose (Day 6)
    - **Part 2 -** Blood samples will be collected to measure metabolites. Collected urine samples may be used to measure metabolites.
  - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples for study drug levels 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
- 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
  - 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

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- 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

Blood Draws

Blood samples will be taken by individual needlesticks, or by an IV catheter placed in a vein in your arm. A catheter is a small tube that may be placed in your arm to make it easier to take blood samples at the required. IV 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.

In Part 2 only, some blood samples may be taken by an investigational automated blood draw device(s) attached to your upper arm(s) using adhesive. Investigational means the blood draw device has not been cleared by the FDA.

There will be about 61 blood draws in Part 1, about 38 blood draws in Part 2, and about 33 blood draws in Part 3. The total amount of blood drawn during the study will be up to 480 mL in Part 1, 290 mL in Part 2 and 160 mL in Part 3. This is equal to about 16 oz., or 2 cups in Part 1 10 oz., or 1 1/4 cups in Part 2, and 6 oz., or 3/4 cups in Part 3. 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 may lead to a low red blood cell count (anemia). Anemia can make you feel more tired than usual.

Once you finish the study, the study investigator may recommend that you take an over-the-counter iron pill or vitamins with iron. This is meant to help you build up your red blood cell count.

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug(s) 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

To date, the study drug has not been administered to humans.

The safety of the study drug has been studied in animals. In these animal studies, no significant risks or safety events of concern were identified, and the study drug did not cause side effects at any of the dose levels that will be used in clinical studies.

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Based on the studies done in animals with moderate to high doses of the study drug, potential risks from treatment with the study drug include:

- Increased respiratory rate (number of breaths per minute)
- Small reductions in heart rate
- Small increases in blood pressure
- Vomiting
- Changes in movement
- Small changes in some blood laboratory measures that play a role in the blood clotting system or in inflammation

You will be monitored for changes in breathing rate, heart rate or blood pressure, as well as for the occurrence of other symptoms or side effects.

Blood and urine samples will be taken on a regular basis to measure and evaluate for any changes in laboratory test results.

Since the use of the study drug is investigational for the treatment of COVID-19 when taken alone or in combination with other medications, there may be other risks or side effects that are unknown. Human clinical and animal studies do not always predict the side effects of experimental medicines that people may experience.

Ritonavir Risks

Like all medicines, this medicine can cause side effects, although not everybody gets them. Also, the side effects of ritonavir when used with other antiviral medicines are dependent on the other medicines.

Very common: may affect more than 1 in 10 people:

• Upper or lower stomach ache
• Vomiting
• Diarrhea (may be severe)
• Feeling sick (nausea)
• Flushing, feeling hot
• Headache
• Dizziness
• Pain in the throat
• Cough
• Upset stomach or indigestion
• A tingling sensation or numbness in the hands, feet or around the lips and mouth
• Feeling weak/tired
• Bad taste in the mouth
• Damage to the nerves that can cause weakness and pain
• Itching
• Rash
• Joint pain and back pain

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Common: may affect up to 1 in 10 people:

- Allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues
- Inability to sleep (insomnia)
- Anxiety
- Increase in cholesterol
- Increase in triglycerides
- Gout
- Stomach bleeding
- Inflammation of the liver and yellowing of skin or whites of the eyes
- Inflammation of the pancreas
- Increase in urination
- Reduced kidney function
- Seizures (fits)
- Low levels of blood platelets (blood cells that help blood to clot)
- Thirst (dehydration)
- Abnormally heavy periods
- Wind (flatulence)
- Loss of appetite
- Mouth ulcer
- Muscle aches (pain), tenderness or weakness
- Fever
- Weight loss
- Laboratory test results: changes in blood test results (such as blood chemistry and blood count)
- Confusion
- Difficulty paying attention
- Fainting
- Blurred vision
- Swelling of the hands and feet
- High blood pressure
- Low blood pressure and feeling faint when getting up
- Coldness in the hands and feet
- Acne

Uncommon: may affect up to 1 in 100 people:

- Heart attack
- Diabetes
- Kidney failure

Rare: may affect up to 1 in 1,000 people:

- Severe or life-threatening skin reaction including blisters (Stevens Johnson syndrome, toxic epidermal necrolysis)
- Serious allergic reaction (anaphylaxis)
- High levels of sugar in the blood (hyperglycemia)

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When you take more than one drug at a time, the side effects can be worse or different than if you take either drug by itself.

Until you know how the study drug(s) 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

Automated Blood Draw Device Risks (Part 2 only)

You may experience discomfort or pain.

You may experience an allergic reaction to the adhesive in the investigational automated blood draw device. An allergic reaction could cause:

- Itching
- Hives
- Rash
- Swelling

Also, the following could occur rarely:

- Difficulty breathing
- Coughing
- Wheezing
- Chest tightness with or without low blood pressure

If not treated promptly, an allergic reaction can be life-threatening. Immediately tell the investigator or clinic staff if you have any of these symptoms.

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 cause sickness or death.

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 (by calling 911 or immediately going to an emergency room) right away 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

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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

Fasting

Fasting could cause symptoms such as:

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

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

Genes are pieces of DNA that, through material called RNA, give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. DNA, RNA, and proteins can be studied as part of genetic research.

This study may involve studying your biology and whether a particular biological feature (including genes) is related to the effects or action of the study drug or to a disease. This may include analyzing all of your genetic information. This is called "whole genome sequencing". Sequencing a gene is like reading a book 1 letter at a time. This is a very thorough way to learn about genes.

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The genetic analysis is for research purposes only. It is not a medical test. This means that the medical importance of the results may not be known. They may not be related to any medical condition.

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

If you do not want genetic testing to be done on your samples, you should not agree to participate in the research described in this document.

Pfizer and researchers will put measures in place to minimize the chance that results from this research could be linked to you. There is always a chance that information from your taking part in the research may be disclosed.

Genetic Information Nondiscrimination Act (GINA)

The GINA is a federal law. It generally makes it illegal for the following to discriminate against you based on your genetic information:

- Health insurance companies
- Group health plans
- Most employers

This law does not protect you against genetic discrimination by companies that sell:

- Life insurance
- Disability insurance
- Long-term care insurance

This law also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Health insurance companies and group health plans may not request your genetic information from this research and it will not be shared with such companies, plans, or employers.

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

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- Redness of the vein
- 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.

ECG and Continuous Heart Monitoring

Possible side effects from having an ECG and/or 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.

COVID-19 Testing

Collection of a swab sample may cause:

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

You are required to disclose any use of anti-inflammatory drug in the last 7 days or any previous history of nasal surgery.

COVID-19: There is a risk of COVID-19 infection when you are in close contact with 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 you cannot be in the study. If you have a positive result it will be reported to the State Department of Health. If you have any questions about what information must be reported, please ask the study investigator or study staff.

Other

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

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Use of Birth Control

Females unable to have children

Women in this study not able to get pregnant include women who:

- Have had their 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.

Females able to have children

If you are sexually active, you must use a highly effective method of birth control. The birth control must be used consistently and correctly from the start of dosing (earlier for hormonal birth control), during the study, and for at least 28 days after the last dose of study drug.

You must not donate eggs for the purpose of reproduction for the duration of the study and for at least 28 days after the last dose of study drug.

Highly effective methods of birth control include:

Low user dependency methods (methods that *do not* rely on you to remember to use them)

- Implantable progestogen-only hormone birth control
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system (IUS)
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has a vasectomy (absence of sperm confirmed)

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 with a female able to have children as your preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent

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Must agree to use birth control as detailed below:

- Agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person.

In addition to male condom use, female partners able to have children may consider an additional highly effective birth control method such as the methods detailed earlier in this document and the following:

- Combined (estrogen and progestogen containing) hormonal contraception
  - Oral
  - Intravaginal
  - Transdermal
  - Injectable

- Progestogen containing hormonal contraception
  - Oral
  - Injectable

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

***Note:** For female partners able to have children, one of the following barrier methods must be used in addition to the **user dependent birth control methods** detailed above:

- Male or female condom with or without spermicide
- Cervical cap, diaphragm, or sponge with spermicide
- A combination of male condom with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods)

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

The effects of the study drug on reproduction are unknown. At this time, it is not known whether the study drug can cause harm to the fetus or whether it is secreted in human milk. Therefore, the study drug should not be administered to pregnant women or women who are breastfeeding. An appropriate method of contraception is required.

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

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If you are currently pregnant, plan to become pregnant, or are breastfeeding a child, you should not join this study.

If you are a man whose partner is currently pregnant or plan to father a child, you cannot join this study.

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

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 doctor who will be taking care of you or your partner during the pregnancy that you took part in this study

The study investigator will ask if you or your pregnancy doctor or your partner or her pregnancy doctor 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 take any medications (including over-the-counter medications, such as medications for cold or allergies, antacids, herbal supplements, St. John's Wort, minerals, or vitamins) within 7 days before the first dose or at any time during the study
  - Before taking any drugs other than the study drug(s), 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 take HRT or some hormonal methods of birth control within 28 days before the first dose. These may not be taken at any time during this study. Depo-Provera® must be discontinued at least 6 months before the first dose
  - Some hormonal methods of birth control may be allowed
- You must not take any investigational drugs within 30 days before the first dose of this study
- If you have received the COVID-19 vaccine, you must have completed the series (2 doses), and at least 7 days should have passed from the time of the 2nd dose to the time of screening
- You may be asked to provide documentation of your childbearing status
- 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

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- 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. of beer, 3 oz. or wine, or 1 oz. of hard liquor
- You must not be using/taking any drugs of abuse (such as marijuana, cocaine, opioids, etc.). Urine tests will be done throughout the study 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 for at least 24 hours before each dosing.
  - You must not smoke more than 5 cigarettes a day or consume an equivalent quantity of tobacco/nicotine containing products
  - You cannot use these products, including vaping, while in the CRU
- 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
- For the (optional) Japanese group you must have 4 biological Japanese grandparents who were born in Japan
- 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 11 to 25 days in a row (Part 1), 12 days in a row (Part 2), and 7 days in a row (Part 3) starting with check-in
  - You may need to stay in the CRU longer if you experience a longer 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 cannot lie down for 4 hours after morning dosing, unless needed for any study procedures
- You will be confined to the procedure room for about 4 hours during continuous heart monitoring, except to use the bathroom (Part 1)
  - You must not do any strenuous activities during the period of monitoring

Diet Restrictions

- You must not eat or drink anything for at least 10 hours before each dose/breakfast in Part 1 and Part 3 and at least 7 hours before the morning dose/breakfast in Part 2. Water is allowed during this time
  - If dosed under fasted conditions (Part 2) no food will be allowed 2 hours prior to and after dosing.
- You must not eat or drink anything for at least 4 hours before most safety laboratory test. Water is allowed during this time

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- When dosing in the fasted state except for 1 hour before and 1 hour after each dose, 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
  - 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
  - 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
- You must be willing to eat the food offered during the study
- Meals (breakfast, lunch, dinner, and evening snack) will be provided at appropriate times

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, and HIV, genetics, sexuality, substance use disorders, mental health disorders, diagnoses and treatment
- **Data from testing and analysis of biological samples** (such as blood or urine) This may also include genetic information

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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)
- IntegReview 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

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- 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

Please check the box next to your choice.

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

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

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
- IntegReview IRB
- Government or regulatory authorities
- Accrediting agencies

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 COVID-19 (or SARS-CoV-2?)
  - 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

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  - 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 be used for other research?

Your Coded Information may be used to advance scientific research and public health in other projects that will take place in the future. At this time, we do not know the specific details of these future research projects. If your biological samples are collected, those samples, and their data, will only be used for other research if you agree under the Additional Consent Request at the end of this document.

Payment for Injury Related to the Study

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

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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 this consent document.

Contact Information

For answers to questions about this research or to report a research-related injury, contact:

Sylvester Pawlak, APRN
Call the 24-hour CRU Telephone Number
203-401-0300

If you are unable to reach anyone at the number listed above and you need medical attention, please go to the nearest emergency room.

You will 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 doctor or healthcare provider if they need more information about the research study to provide the best treatment for you.

You may contact IntegReview if:

- You want to talk to someone other than the study investigator or study staff
- You have concerns or complaints about the study
- You want to ask questions about your rights as a study participant

IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human participants taking part in research studies. IntegReview requires that all concerns/complaints be submitted in writing. These will be reviewed at one of their meetings.

Mailing Address:	**OR**	**Email Address:**
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway, Suite 320 Austin, Texas 78704		integreview@integreview.com

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding participant safety, contact our office at:

512-326-3001 or
toll-free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information provided in this informed consent document (ICD) and has given approval for the study investigator to do this study. This does not mean IntegReview has approved your personal participation in this study. You must consider the information in this consent document for yourself and decide whether or not you want to be in the study.

Link to Additional Information

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.

Payment for Taking Part in the Study

Valid proof of a Social Security Number (SSN) is required. This is needed before any payment can be made.

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. Additional travel pay may be available for this study.

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.

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 will not be allowed to be in any future studies
- You will be removed permanently from our active database

Screening Payments

The screening payment(s) is listed below. This is for travel expenses to and from screening procedures. 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).

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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
- If total payment by Pfizer is $600.00 or more in a calendar year, your payment will be reported to the Internal Revenue Service in accordance with Federal tax law; in some countries compensation may not be allowed due to immigration status
- 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
- You may be offered transportation to and from the study site at no additional charge to you

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 1 ONLY		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$239.00	25
Follow-Up Visit to CRU	$250.00	0 planned
Time Between Discharge and Follow-Up Phone Call	$100.00	4 weeks
Completion Bonus	$1700.00	
Total Payment	$8075.00	

STUDY PARTICIPANTS- PART 2 ONLY		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$265.00	12
Follow-Up Visit to CRU	$250.00	0 planned
Time Between Discharge and Follow-Up Phone Call	$100.00	4 weeks
Completion Bonus	$895.00	
Total Payment	$4475.00	

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STUDY PARTICIPANTS- PART 3 ONLY		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$260.00	7
Follow-Up Visit to CRU	$250.00	0 planned
Time Between Discharge and Follow-Up Phone Call	$100.00	4 weeks
Completion Bonus	$630.00	
Total Payment	$2850.00	

BACK-UP PARTICIPANTS PART 1, PART 2, PART 3	
Type of Activity	**Payment per Activity**
Overnight Stay*	$300.00
Daytime Stay	$190.00

*Overnight stay rates include an increase for COVID restriction inconveniences

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, IntegReview IRB, 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.

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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. You can then decide if you still want to be in the study.

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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 THIS CONSENT DOCUMENT

- You will get a 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 SSN/Tax ID Card)

_____
Signature of Adult Study Participant Date

_____
Printed Name or Initials of Person Explaining Informed Consent

_____
Signature or ALPHA NUMERIC CODE of Person Explaining Informed Consent Date

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ADDITIONAL CONSENT REQUEST (OPTIONAL)

Use of Biological Samples for Additional Research

Pfizer would like your permission to use some or all of the samples collected in this study for additional research that may or may not be related to the study. This additional use of your samples is called "**Additional Research**."

This Additional Research is optional and you do not have to agree. You may take part in the study and contribute samples for use in the study even if you do not want your samples to be used for Additional Research.

If you decide to take part in this Additional Research, you do not have to provide any new samples. Researchers will use samples that already have been collected during the study.

There is no penalty or change to your regular medical care if you decide not to take part in this Additional Research.

1. What is the purpose of this Additional Research?

The aim of this Additional Research is to use these biological samples and the information obtained from them to understand diseases and to advance science. This includes the development of other medicines or treatments.

- This Additional Research might involve learning more about your biology. It may involve studying biological substances in your sample(s), including your genes.
- The Additional Research might include exploratory research of any disease or condition

2. What are the possible risks of this Additional Research?

There is always a chance that information from your taking part in the Additional Research may be disclosed. Pfizer and researchers will put measures in place to minimize the chance that results from this Additional Research could be linked to you.

The testing of DNA and/or RNA risks language in the consent document for the study applies to this Additional Research.

3. What are the possible benefits of this Additional Research?

This Additional Research is for research purposes only. There is no direct benefit to you from taking part. Information from the Additional Research may help other people in the future and help in the development of new medicines or treatments.

4. What if I agree to this Additional Research and then change my mind?

You can change your mind at any time about allowing your biological samples to be used for this Additional Research. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study investigator if you would like to end your participation in the Additional Research.

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5. What will I have to pay for if I take part in this Additional Research?

There will be no charge to you for allowing your samples to be used for this Additional Research.

6. Will I be paid if I consent to this Additional Research?

You will not be paid for taking part in this Additional Research. Pfizer may use information from this Additional Research to develop products or processes, from which Pfizer could make a profit. There are no plans to pay you or provide you with any products developed from this Additional Research. Pfizer will own or have rights to all products or processes that are developed using information from your samples.

7. What will happen to my personal information?

All information concerning the confidentiality, use, and disclosure of your information contained in the main consent for the drug study applies to this consent as well.

It is possible that results from the Additional Research may be included in:

- Further applications to government agencies to market other medicines or devices
- Ethics committees/IRBs involved in research

Pfizer may share the samples and data from the samples with third parties in order to perform the Additional Research described above. The third parties may include other researchers and collaborators at institutions and companies.

8. Where can I find additional information about this Additional Research or the results of this Additional Research?

It may not be possible to link the results of the Additional Research to individuals, including you. Pfizer does not plan to give any information generated during the Additional Research to:

- You
- The study investigator
- Your personal doctor
- Your family
- Your employer
- Any insurance company

9. Contact Information

The study investigator or study staff will answer your questions or concerns regarding the Additional Research. The consent document for the study provides contact information if you need to reach the study investigator or study staff or wish to speak with someone not involved with the Additional Research.

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10. Decision to Participate in Additional Research

Below **please check the box next to your choice** regarding whether to take part in the Additional Research. Thank you for considering whether to participate.

☐ I agree to allow my samples to be used for Additional Research for the purposes described above.

OR

☐ I do NOT agree to allow my samples to be used for Additional Research for the purposes described above.

Signatures

- I have read and understand this Additional Consent Request.
- I have had enough time to ask questions and decide whether or not to participate.
- I understand that taking part in the optional uses described in this Additional Consent Request is voluntary.
- I do not give up any of my legal rights by signing this consent document.
- I have been told that I will receive a signed and dated copy of this document.

_____
Printed Name of Adult Study Participant

_____
Signature of Adult Study Participant Date

_____
Printed Name or Initials of Person Explaining Informed Consent

_____
Signature or ALPHA NUMERIC CODE of Person Explaining Informed Consent Date