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INTEGREVIEW IRB
NOVEMBER 12, 2019

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Pfizer Inc
NUMBER AND NAME OF STUDY:	C4041001; "A PHASE 1, RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO-CONTROLLED, FIRST-IN-HUMAN STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF SINGLE ASCENDING ORAL DOSES OF PF-06842874 ADMINISTERED AS AN IMMEDIATE-RELEASE FORMULATION TO HEALTHY ADULT PARTICIPANTS AND AN OPEN-LABEL ASSESSMENT OF THE RELATIVE BIOAVAILABILITY OF A MODIFIED-RELEASE FORMULATION OF PF-06842874"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY INVESTIGATOR):	Mary Powell-St. Louis, M.D., MPH
TELEPHONE NUMBER 24 HOURS:	203-401-0300

INTRODUCTION

You are here today as a possible volunteer in a drug research study sponsored by Pfizer Inc. Whether or not you are in this study is strictly up to you. You may refuse to take part in this research study. 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.

INFORMATION ABOUT THE STUDY DRUG

PF-06842874 will be referred to as "the study drug" in the rest of this document.

This will be the first time that the study drug will be given to humans.

The study drug is a new investigational drug being studied to treat people with pulmonary (lung) arterial hypertension (PAH). An "investigational drug" is a drug that has not been approved to treat disease. PAH is a disease that affects the arteries of the lungs, making them smaller and less able to carry blood. This causes the heart to work harder to pump blood through the lungs which causes high blood pressure (hypertension) on the right side of the heart. This is different from "typical" high blood pressure (as measured, for example, in your arm) which comes from increased pressures in the left side of the heart.

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This research study will be the first time the study drug will be given to people. The effects (both good and bad) of the drug in people are therefore not known. The main goal of the current study is to assess the safety and tolerability of the study drug in people. This will be done by first giving people a low dose of the drug that is not expected to have any activity or negative side effects. The dose will then be increased step-wise and we will be looking for any unwanted (negative) side effects. Doses will be increased as long as the study drug has acceptable safety, tolerability, and drug levels in the blood.

The first (starting) dose of study drug will be 3 mg. If the dose is tolerated without significant side effects and the levels in the blood are acceptable, then the dose in later groups may be increased in stages by no more than approximately 3-fold (for example, 3, 10, 30, and 100 mg) to a planned maximum dose of 600 mg, but higher doses may also be given. You will only receive 1 dose of study drug or placebo (which is something that looks like the study drug but has no activity). Doses may also be repeated, increased, or lowered based on study drug safety or blood levels. Study drug and placebo will be given as a suspension (cloudy liquid), which you will drink. Study drug also may be given as 1 or more tablets that you will swallow.

The liquid doses 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 doses. The liquid doses are an immediate-release (IR) formulation which means that the study drug is expected to be absorbed (taken into the blood from the gut) quickly.

The study drug tablets are special preparations designed to release the drug slowly as it passes through your intestines (gut). This allows the study drug to be absorbed by your body over a period of time instead of all at once. These special tablet preparations of study drug are known as modified-release (MR) tablets.

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

STUDY DESIGN

The study has 2 parts (Part A and Part B).

<u>Part A</u>

Up to 10 groups of 8 participants each will be in this part of the study. If you are accepted into this part of the study, you will receive a single oral (by mouth) dose of study drug or placebo. The study drug and placebo are planned to be given as a suspension (a cloudy fluid containing very small particles of study drug in liquid).

If you are accepted into this part of the study, you will be randomly assigned (like the flip of a coin) to receive either the study drug or placebo. You have about a 1 in 4 chance of being on placebo.

In most cases, study drug will be given under fasting conditions (on an empty stomach before breakfast). In some groups in this part, the study drug or placebo may be given with food (shortly after eating a full breakfast).

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Part B

Part B has 3 groups of up to approximately 6 participants. The number of participants may change based on the information from Part A of the study. If you are accepted into this part of the study, you will receive a single oral dose of study drug. Study drug will be given as tablets. Planned doses are 25 mg and 300 mg. Doses may change (made higher or lower) based on the information from Part A or previous groups in Part B of the study, but Part B doses will be the same or lower than doses administered in previous parts of the study. In one of the groups, study drug may be given with food.

The study investigator or sponsor may decide to remove you from the study at any time if it seems you are having a significant undesirable (negative) reaction to the study drug.

PURPOSES OF THE STUDY

There are 6 purposes of this study:

1. To see how well single doses of the study drug are tolerated as the dose is increased, if there are significant side effects, and how healthy adult participants feel after taking single doses of the liquid (IR) and/or tablet (MR) forms of the study drug
2. To measure the amount of the study drug in your blood over time after you have taken a single dose
3. To compare the average amount of study drug in the blood over time after a single oral dose given as either the liquid or tablet forms
4. To evaluate additional measurements of the study drug in the blood after single oral doses of the IR or MR formulations
5. To evaluate the average effect of food on the amount of study drug absorbed (taken into) the blood after dosing
6. To collect exploratory samples for biobanking
    - Biobanking is the collection and storage of blood samples for possible future testing

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

You will be in this study up to about 36 days. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

- 1 dosing period
- 3 overnight stays
- 1 follow-up visit to the clinic (about 7-10 days after the dose)
- 1 follow-up phone call (about 28-35 days after the dose)

Up to approximately 80 healthy male and female participants will be in part A of the study, and up to approximately 18 healthy male and female participants will be in part B of the study. Females must not be able to have children.

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WHEN ARE YOU ELIGIBLE TO PARTICIPATE IN ANOTHER DRUG STUDY?

The decision for when you are eligible to screen for another study is based on information from this study. You may be eligible to dose in another study as soon as 30 days after the last dose of study drug. This information is true for most drugs. Some drugs may be present in your body longer and that may mean you may have to wait longer before entering into another study. These results are usually known after your last regularly scheduled blood sample is tested. We will always tell you this as soon as possible. We will let you know 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. Your safety while in these studies is our main concern.

TO BE IN THE STUDY

You cannot screen for this study if you are currently in another research study. This includes being in the follow-up visit period of another research study.

To be in this study, your medical history and screening test results must be acceptable. Also, you must meet each of the following conditions:

- You must be a healthy male or female between the ages of 18 and 55 at the time of signing this consent document
- Females must be unable to have children and meet 1 of the following criteria:
  - Postmenopausal (at least 12 consecutive months without a period with no other medical cause and a blood test confirming that you are unable to have children)
  - Uterus and/or both ovaries removed (documented)
  - Both fallopian tubes removed (documented)
  - 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
- You must be willing and able to comply with scheduled visits, the study plan, lab tests, and other study procedures
- You must have a body mass index (BMI) between 17.5 and 30.5 and weigh more than 50 kg (110 lbs)
- You must be capable of giving informed consent and have signed and dated this consent form
- You must not have evidence or a history of blood, kidney, glandular, lung, stomach, intestine, heart, blood vessel, liver, psychiatric, nerve, or allergic disorders (including drug allergies)
  - Untreated seasonal allergies without symptoms are allowed
- You must not have any condition that might affect your body's ability to absorb drugs (for example, gastric bypass surgery, gall bladder removal)
- You must not have a history of, or a current, positive result for any of the following blood tests: human immunodeficiency virus (HIV), Hepatitis B surface antigen (HepBsAg), Hepatitis B core antibody (HepBcAb), or Hepatitis C antibody (HCVAb)
  - A positive Hepatitis B surface antibody (HepBsAb) due to vaccination is allowed
- You must not have benign ethnic neutropenia (low neutrophil [type of white blood cell] count in individuals of African descent) or cyclic neutropenia (recurrent low neutrophil count)
- You must not have any medical or psychiatric condition, including recent (within the past year) or active suicidal thoughts or behavior, or lab abnormality that could increase your risk of being in the study or receiving the study drug
  - You must not have any condition or lab abnormality that could interfere with the interpretation of the study results and, in the judgment of the study investigator, make you an inappropriate subject for this study

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- You may not take any prescription or nonprescription drugs or nutritional (dietary) or herbal supplements for at least 7 days before the first dose, or at any time during this study
  - Tylenol® (acetaminophen) may be used at doses of less than or equal to 1000 mg a day
    - Its use must first be approved by the study investigator
  - Other nonprescription medicines that are not thought to affect your safety or the overall study results may be allowed on a case-by-case basis if first approved by the study investigator
- Females taking hormone replacement therapy must be willing to discontinue therapy at least 28 days before the first dose, and remain off therapy for the duration of the study
- You must not have taken any investigational drugs for at least 30 days before the first dose of this study
  - You must not be in another drug study at any time during this study
- You may only participate in 1 part of this study
- You cannot be in this study if you are using/taking any drugs of abuse. A urine test will be done to check for drugs of abuse
- While in this study please do not eat anything that contains poppy seeds, as they may cause a positive drug test
- Your screening blood pressure while lying down must be less than or equal to 139/89 mm Hg
- Your screening ECG (electrocardiogram that measures the electrical activity of the heart) must be normal
- You must not have any of the following laboratory test abnormalities:
  - Liver enzymes (indicate how your liver is working) greater than or equal to 1.25 times the upper limit of normal
  - Total bilirubin greater than or equal to 1.5 times the upper limit of normal, or a direct bilirubin (for subjects with Gilbert's syndrome – a harmless mild liver condition in which the liver does not properly process bilirubin) greater than the upper limit of normal
  - Hemoglobin (protein in red blood cells that carries oxygen) less than or equal to 14 gm/dL (males) or 13 gm/dL (females)
  - Neutrophils (a type of white blood cell) less than 1500 cells/mm^3
- You must not have a history of excessive alcohol use, binge drinking, or use of any illicit drug or drug dependence within 6 months before screening
  - Binge drinking is defined as a pattern of 5 (males) or 4 (females) or more alcoholic drinks in about 2 hours
  - Alcohol intake should not exceed 14 units/week
    - A drink (unit) is defined as 8 oz of beer, 3 oz of wine, or 1 oz of hard liquor
- Study staff may check your breath for the presence of alcohol. If alcohol is detected, you will not be allowed to be in this study
- You must not have donated (such as at a blood bank) a unit of blood (except plasma donations) for at least 60 days before dosing
- You must not donate any blood or blood products at any time during this study and for at least 4 weeks after your last blood draw
- You must not have a history of sensitivity to heparin (a substance that stops blood from clotting) or of low platelets (cells that help with blood clotting) as a result of heparin
- You must be willing and able to comply with the activity and diet restrictions of the study (detailed later in this document)
- You must not be a staff member of the CRU directly involved in the study, a relative of a staff member at the CRU directly involved in the study, a staff member of the CRU supervised by the study investigator, or a Pfizer employee, including family members, directly involved with the study

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- Female participants must not be able to have children, pregnant, or breastfeeding
- Male participants must not donate sperm for the duration of the study through at least 90 days after the last dose
- During the study, it is required that all male participants use condoms to prevent the potential transfer of drug through the semen to their partner beginning with the first dose of study drug through the duration of the study and for at least 90 days after the last dose, as the effects of the study drug on sperm are unknown

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to:

- Sign this consent form
- Give your race, age, gender, and ethnicity
- Review the study entry criteria
- Review the use of birth control (males only)
- Give your medical history
  - If you are not completely honest with your medical history, you may be harmed by being in this study
- Give your drug, alcohol, and tobacco use history
- Tell the study staff if you have taken in the past 28 days, or are taking, any over-the-counter or prescription drugs, vitamins, or dietary or herbal supplements

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

- Vital signs (blood pressure and heart rate while lying down)
- Height and weight
- Safety lab tests (blood and urine)
  - Includes blood tests for HIV, HepBsAg, HepBcAb, and HCVAb
- Urine to test for drugs of abuse (illegal and prescription)
  - If this 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
- The study investigator may decide to do an alcohol breath test
- ECG (single measurement)
- Complete physical exam. This may be done at screening or when you check-in for the dosing period of the study
- You will be asked "How do you feel?"
- Females who have not had a period for at least 12 consecutive months will have a blood hormone test that will confirm they cannot have children

HIV and Hepatitis Testing:

As required by this study, and if anyone is exposed to your blood, you will have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS). If you have a positive HIV or hepatitis test, you cannot be in/remain in the study.

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If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling.

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

Positive results for HIV or hepatitis tests or for other infections, or possibly having certain infections, may have to be reported to the State Department of Health. 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 intended to be private, complete confidentiality 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:

During the study, you will complete all the items listed below:

- Before being brought to the second floor of the clinic for your in-house stay, your belongings will be thoroughly searched
  - You will be asked to empty your bags and set all your belongings on the table so the staff can go through them
  - You will be asked to empty your pockets, remove your shoes and hat, if you are wearing one, and you will be patted down
  - You will be scanned with a metal detector wand
- Review the study entry criteria
- Updates to your medical history, including drug, alcohol, and tobacco use
- Updates in any medications used since screening
- Blood and urine samples will be collected at various times throughout the study
  - The blood and urine samples will be used for safety labs
    - Any leftover blood and urine from the samples collected for safety labs may also be used for 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
  - Blood samples will also be used to measure the levels of study drug in your blood
    - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used to evaluate safety or efficacy (ability to produce a desired effect) aspects related to concerns arising during or after the study, for metabolite identification (by-product(s) or end product(s) of a drug produced as the body processes a drug) and/or evaluation of the laboratory test(s) used to measure the study drug, as well as for other internal exploratory purposes
- 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)
- Urine samples to test for drugs of abuse will be collected at the time of check-in and may be collected at various times throughout the study
  - If this test is positive, you will not be allowed to continue in the study

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  - 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
- The study investigator may decide to do an alcohol breath test at check-in and at any time during the study
- A complete physical exam will be done at study check-in, if it was not done at screening
  - A limited physical exam may be done at various times throughout the study
- The use of proper birth control will be confirmed/reviewed at study check-in and during the follow-up visit and follow-up phone call (males)
- Blood pressure and heart rate will be measured while you are lying down at various times throughout the study
- Body temperature will be measured at check-in
- You will be asked "How do you feel?" each day
- An intravenous (IV) catheter may be placed in a vein in 1 of your arms for blood collection
- ECGs (triplicate measurements taken about 2-4 minutes apart) will be done at various times throughout the study
  - It may be necessary to shave 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 a minimum of 8 hours after dosing in Part A of the study. There will also be a period of at least 2 hours where data will be collected before dosing
  - This involves the attachment of a small box like unit (transmitter) to your chest
  - The box is attached by a few wires (like those of an ECG)
  - The monitor sends information about your heart's activity by a radio signal to a central monitor
  - You may not sleep during the 2 hours of continuous monitoring done before dosing
  - You will be confined to the procedure room for at least the first 4 hours after dosing while attached to the monitor
  - You will be required to keep the box with you during the monitoring period (8 hours)
- You will return to the CRU for a follow-up visit between 7 and 10 days after the dose
- You will receive a follow-up phone call between 28 and 35 days after the dose

A. Dosing Schedule:

Part A

Dosing is planned as follows:

GROUP	NUMBER OF PARTICIPANTS	PERIOD 1
A1	8	3 mg* or placebo
A2	8	10 mg* or placebo
A3	8	30 mg* or placebo
A4	8	100 mg* or placebo
A5	8	300 mg* or placebo
A6	8	600 mg* or placebo
A7	8	TBD
A8	8	TBD
A9	8	TBD
A10	8	TBD

*The starting dose in Group A1 will be 3 mg. Subsequent doses in all following groups may be adjusted

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based on observed safety, tolerability, and study drug levels.
TBD – to be determined

Dosing formulation planned for Part A is the IR solution.

Neither you nor the study staff will know which of the above you are receiving. If necessary, in case of a medical emergency, the identification of the study drug will be made available to the clinic study investigator.

Part B

Dosing is planned as follows:

GROUP	NUMBER OF PARTICIPANTS	PERIOD 1
B11	6	25 mg*
B12	6	300 mg*
B13	6	300 mg* - fed

*Doses may be adjusted based on observed safety, tolerability, and study drug levels.

Dosing formulation planned for Part B is the MR tablet(s). The number of tablets for an MR dose will range between 1 and 6.

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

Parts A & B

On the dosing day, doses (or breakfast, if dosing under fed conditions) will be given after an overnight fast (no food or drink except water) of at least 10 hours.

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. Participants may receive an additional 100 mL (a little over 3 oz) of water if needed.

You may be asked to wear gloves during dosing. Tablet(s) must be swallowed whole. Liquid must be completely swallowed. We will check your mouth after each dose to make sure the dose has been swallowed.

When dosing under fed conditions, you will receive a high-fat breakfast about 30 minutes before dosing. It should be completely eaten over 25 minutes. Dosing will follow within 5 minutes of completing breakfast.

An example of a high-fat breakfast would be: 2 eggs fried in butter, 2 strips of pork bacon (or 50 grams of meat or sausage), 2 slices of toast with butter, 4 oz of hash brown potatoes, and 8 oz of whole milk. Breakfast should be eaten completely in 25 minutes. By reading and signing this consent form, you are agreeing to eat all the food listed in this breakfast menu.

This is a research study. The study drug will be given to you only during this study and not after the study is over.

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B. Blood Samples:

During the study, blood samples will be taken by individual needlesticks or by a catheter put directly into a vein in your arm. The catheter procedure consists of putting a small tube in your arm to take blood when required. Catheters are used at the judgment of the study investigator or when required by the study plan, not at the request of the subject.

There will be about 18 blood draws. The total amount of blood drawn during the study will be about 120 mL. This is equal to a little more than 4 oz, or about 1/2 cup. 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, adequate rest and good eating habits are recommended.

YOUR RESPONSIBILITIES

Activity Restrictions:

- You will be confined to the CRU for 3 days, starting with check-in
  - If a prolonged drug effect is noted and your safety is a concern, you may need to remain in the CRU longer
  - The study investigator or study staff will decide when you can leave the CRU
- You must not do any strenuous exercise (for example, heavy lifting, weight training, calisthenics, or aerobics) for at least 48 hours before each blood collection for safety labs
  - Walking at a normal pace is allowed
- You must call the CRU at the 24-hour phone number listed on the first page of this consent form for approval before taking any drugs other than the study drug
  - You must report all such drugs taken during the study to the study staff
- You must not use tobacco or nicotine-containing products for at least 24 hours before dosing and while confined to the CRU
- Lying down is not allowed for 4 hours after dosing, unless needed for any study assessments
- You will be confined to the procedure room for the first 4 hours after dosing (Part A only) during continuous cardiac monitoring, except to use the bathroom
- You will be advised to avoid direct sunlight exposure or any high-intensity ultraviolet (UV) light exposure from the day of dosing until the follow-up contact
  - You should apply sun cream/lotion with a sun protection factor (SPF) of greater than or equal to 50, as appropriate

Diet Restrictions:

- You must not eat or drink anything, except water, for at least 10 hours before collection of the pre-dose blood sample for study drug and 4 hours after dosing
- You must not eat or drink anything, except water, for at least 4 hours before each safety laboratory test
- Except for 1 hour before and 1 hour after dosing, you may drink water freely
  - If dosing under fed conditions, you may drink water freely before dosing
- You must not eat or drink anything with alcohol 24 hours before check-in through the collection of the last blood sample for study drug

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  - You must not drink red wine from 7 days before the first dose through collection of the last blood sample for study drug
- You must not eat or drink anything with caffeine from 24 hours before dosing through collection of the last blood sample for study drug
  - Food and beverages with caffeine include, but are not limited to, chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything containing grapefruit or grapefruit-related citrus fruits (for example, Seville oranges, pomelos, fruit juices), including smoothies, from 7 days before dosing through collection of the last blood sample for study drug
- Lunch will be served about 4 hours after dosing
- Dinner will be served about 9-10 hours after dosing
- Evening snacks may be allowed at appropriate times
- Meals will be provided as appropriate on the days you are not dosed

POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY DRUG AND PROCEDURES STUDY DRUG

This is the first time this drug will be given to people.

The safety profile of the study drug at this time only reflects data from studies done in animals (rats and dogs) for up to 4 weeks in length. Animal studies do not always predict the side effects people may experience. The actual safety of the study drug won't be known until it has been given to people. However, there are 3 drugs already approved that work in a way like the study drug. Experience with these similar drugs may provide clues about important negative effects people may have after taking the study drug.

The study drug works by preventing some types of cells in the body from dividing to make new cells. The hope is that this effect on cells in diseased organs and tissues will be greater than the effects on normal cells in the body. The effects of the study drug to prevent normal cells from dividing can produce undesirable (or negative) effects (also known as adverse effects).

The main negative side effects seen in the animal studies with the study drug (and also with approved drugs that work in the same way as the study drug) were the following:

1. <u>Effects on blood forming cells in the bone marrow in both male and female animals</u>

In the bone marrow of rats and dogs, high doses of the study drug (relatively higher than you will receive) were found to decrease the numbers of early cells that eventually give rise to the white and red blood cells seen in the blood. This can lead to lower numbers of mature white and red blood cells in the blood. Decreases in white blood cells can increase the risk of infection. Decreases in red blood cells can lead to anemia which makes it harder for the body to get oxygen from the lungs to the tissues where it is needed to make energy for cells to work properly. These effects on the bone marrow cells were found to get better after the drug was stopped.

Experience with other drugs that work like the study drug has shown that with repeat dosing decreases in white blood cells, particularly a type of white blood cell known as neutrophil, can happen. Sometimes, the number of neutrophils has been seen to drop to critically low levels that increase the risk of infection. Decreases in other types of white blood cells (lymphocytes) and platelets (a type of white cell that helps stop bleeding and form clots) have also been seen with these other drugs. Anemia due to decreases in the

production of red blood cells has also been seen. Experience with these other drugs that work like the study drug suggests that the effects on the bone marrow and blood cells counts will get better when people stop taking the drug.

None of the effects on the bone marrow or number of cells in the bloodstream seen in animals with the study drug, or in humans with other drugs that work like the study drug, are likely to happen with single doses of the study drug. The number of red and white blood cells in the bloodstream are easily followed using laboratory tests. If you participate in the study, your blood cell counts will be checked with laboratory tests.

2. Effects on the testes (testicles) in male animals

In studies in male rats and dogs, the study drug was found to cause negative effects on the cells that make sperm in the testes (testicles) at all doses tested. Negative effects of the study drug on the testes could lead to infertility or problems with the ability to father children after long-term dosing with the drug. The negative effects in the testes appeared to get at least somewhat better in animals allowed to recover for some time after the study drug was stopped.

Data in animals with other drugs like the study drug showed similar effects on the testes as the study drug. These data also suggest that these changes in the testicles may get better when people stop taking the drug. Negative effects on sperm production that would cause problems with the ability to father children are very unlikely to be an issue with single doses of the study drug. To minimize any potential negative effects on male sperm production, participants in the current study will only receive a single dose of study drug or placebo.

3. Other potential effects

Drugs that work like the study drug have been approved for the treatment of breast cancer. In these cancer patients, the drugs are used with another drug that works to reduce the effects of female sex hormones on the cancer. Common negative effects seen in clinical studies with the other drugs have included:

- Mouth pain
- Nausea
- Vomiting
- Diarrhea
- Decreased appetite
- Increases in the rate of infections
- Increases in blood levels of liver proteins (which may be a sign of damage to liver cells)

It is not known if these negative effects will also be seen in people given the study drug. You should tell the study investigator right away if you experience any of the effects listed above, in addition to the following:

- Signs of infection such as:
  - Fever
  - Productive cough
- Easy bleeding or difficulty with bleeding stopping
- Signs of liver problems or bleeding in the bowel, such as:
  - Yellowing of the white parts of the eyes

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- Dark urine
- Tarry (sticky, black-colored) or clay-colored stool

A rare type of lung inflammation has happened infrequently in patients taking drugs similar to the study drug together with a hormonal treatment for their cancer for long periods of time. Rarely, this lung disease has been severe, life-threatening, or has resulted in death. This type of lung disease is not expected to happen with short (days to a few weeks) length of treatment with the study drug. Patients receiving repeat doses of study drug for long periods of time will have chest X-rays to monitor for changes in the lungs. People taking the study drug should tell the study investigator right away if they develop a chronic cough or become more short of breath.

If you experience any of the above side effects, contact the study investigator and/or seek medical care. If you do not understand what all these side effects mean, please ask the study investigator or study staff to explain them to you.

The study drug may make your skin more sensitive to light. You will therefore be asked to avoid exposure to sunlight throughout the study, through the follow-up contact. This includes:

- Tanning booths
- Tanning beds
- Sunlamps

If exposure to sunlight cannot be avoided, measures should be taken to minimize sunlight exposure through the use of:

- Broad spectrum UVA/UVB sunscreens with an SPF of 50 or higher
- Protective clothing
- UVA-/UVB-blocking eye protection

Because the study drug is investigational, all its side effects are not known. There may be rare and unknown side effects, including reactions that may be life-threatening. It is important that you report all side effects that you experience as soon as they occur, regardless of whether or not you believe they are caused by the study drug.

All drugs have a potential risk of an allergic reaction which, if not treated promptly, could become life-threatening. You should get medical help and contact the study investigator right away if you think you have any of the following symptoms of a serious allergic reaction:

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

Other allergic reactions may include:

- Itchiness
- Rash
- Hives

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- 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

Any subject who experiences a significant side effect during the study may have the following additional procedures done:

- A heart monitor may be attached to the chest for a continuous reading of heart rhythm and rate
- Vital signs, including blood pressure, may be measured often
- A monitor may be placed on a finger to sense the amount of oxygen in the blood
- A catheter may be inserted into a vein in your arm so that you may be given IV fluids and/or medications
- Other tests or treatment may be administered (given) as necessary for your safety including, but not limited to, additional blood draws, collection of urine, stool, or other bodily fluids
    - Depending on the severity of your symptoms, you may be referred to outside medical providers or a hospital for additional 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

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

ADDITIONAL RISKS OR DISCOMFORTS

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

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.

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

- You
- The study investigator
- Any insurance companies
- 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):

A Federal law, called the GINA, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not ask for your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment

You should know that this Federal law does not protect you from genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Blood Samples and IV Catheter (if used):

Possible side effects of having your blood drawn or an IV catheter inserted into a vein in your arm include:

- Bleeding at the site of the needle puncture
- Bruising
- Feeling faint
- Rarely infection or blood clot
- Redness of the vein and/or pain

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:

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- 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.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on the following are not known:

- Sperm
- Pregnancy
- Unborn child
- Breastfeeding child

If you are currently pregnant or breastfeeding a child, you should not join this study. If you are a male whose partner is currently pregnant or who plan to father a child, you should not join this study.

Birth control methods, even when used properly, are not perfect. If your partner becomes pregnant during the study, or you want to stop your required birth control during the study, you should tell the study investigator immediately. You may be withdrawn from the study if you stop using birth control.

Females

Women in this study should not be able to get pregnant. Women who can be in this study could include:

- Postmenopausal (at least 12 consecutive months without a period with no other medical cause and a blood test confirming that you are unable to have children)
- Uterus and/or both ovaries removed (documented)
- Both fallopian tubes removed (documented)
- 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 **90 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

OR

- Must agree to use birth control as detailed below:

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- Must 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 who are able to become pregnant are recommended to use an additional highly effective birth control method such as:

- Hormonal contraception
  - Implantable
  - Oral
  - Intravaginal
  - Transdermal
  - Injectable
  - Intrauterine hormone-releasing system (IUS)
- Intrauterine device (IUD)
- Bilateral tubal occlusion (tubes blocked)/bilateral tubal ligation (tubes tied)

A condom may break or leak when having sexual intercourse with a female partner able to have children who is not currently pregnant.

Pregnancy Follow-Up:

If your partner becomes pregnant during the study or within at least 28 days after you have stopped taking the study drug, please tell the study investigator immediately. Please also tell the doctor who will be taking care of your partner during the pregnancy that you took part in this research study. The study investigator will ask if your partner or her pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If your partner agrees, this information will be collected for safety monitoring follow-up.

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from being in the study. Information from this study may benefit persons with PAH in the future.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

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

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY (CONFIDENTIALITY)

The clinic staff will record:

- Your medical history
- The dose(s) you receive
- The results of exams and tests done during the study

Your name will not appear in the study data. Instead you will be identified by a subject-identification number. The information from the study data may be shared with others.

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Your clinic records may include:

- Health information about you
- Documents that directly identify you

People from the groups listed below may need to look at your clinic records to make sure that the study information is correct and that the study was run as it should have been.

These reviews may take place during the study or after the study is over.

Your study information may be shared with the following people or groups:

- Pfizer Inc or its representatives, including its auditors and companies it hires to provide study-related services
- IntegReview IRB, the institutional review board (IRB) that approved this study, and any other committees responsible for overseeing the research
- Researchers who are conducting this study at other study centers
- Government health agencies (such as the Food and Drug Administration [FDA]) in the United States (US) or other countries
- Accrediting agencies

People from these groups may get information from your study data. Or, they may review your clinic records. Because of the need to share information with these people, it may not be possible to keep your identity a secret.

Pfizer will use and share your information only for research or legal reasons or to write research reports. In addition, Pfizer may:

- Capture data from electronic devices if you complete the consent process using the eConsent tablet. This information may include data about your use of the eConsent tablet such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, and your electronic signature.
- Look at the study data later
- Add your information to information from other studies for other research reasons. However, your name will never appear in any reports, or in any future communication by Pfizer.

By signing this consent form, you agree to allow the use of your study information even after you leave the study

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Please note the following information regarding the delivery of push notifications and text messages:

- The sponsor, or a company working for the sponsor, occasionally may send push notifications and text messages using an automated system to remind you of upcoming appointments, medication reminders and missed doses, or other study-related information
- To discontinue receiving text messages, please contact the Pfizer New Haven CRU at 800-254-6398

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- Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier, so please contact your wireless phone provider to inquire 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 research study
- The push notifications or text messages received through this program may appear on your mobile phone screen as soon as they are received, 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

PAYMENT FOR INJURY RELATED TO THE STUDY

If you experience a research injury, the clinic 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.

Remember that you must call the study investigator listed on the first page of this consent form immediately if you experience a research injury. 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 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), in accordance 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 form.

WHOM TO CONTACT

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

Mary Powell-St. Louis, M.D., MPH
Call the 24-hour Clinic 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 clinic 24-hour phone number

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

If you do not want to talk to the study investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. 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 subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

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

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject 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 form 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 form for yourself and decide whether or not you want to be in the study.

PAYMENT FOR BEING IN THE STUDY

Valid proof of a Social Security Number is required before any payment is released.

The amount of payment is based on a number of things including the length of the study.

All payments will be made in US 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.

You will be paid $175.00 for travel expenses to and from screening. You will receive this payment within 2 weeks of screening. If you test positive for drugs of abuse or if you leave the screening early, you will not be paid the $175.00. Travel pay for this study has been included in the subject payment. Additional travel pay is not available for this study.

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

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- You will be removed permanently from our active database

The payment for completing the entire study will be up to $1475.00. If you do not follow instructions your payment may be less.

If we ask you to return for additional tests, you will be paid $250.00 for each trip to the clinic. During times that you are confined to the clinic, you will not be paid more for repeat or added tests.

If you discontinue from the study or if you are taken out of the study early, you will be paid for the time you completed. You will not be given the study completion bonus if you drop out of the study early.

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.

Pfizer may use information resulting from the study or samples collected in the study to develop products or processes from which it may make a profit. 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 research study.

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

Study Participants:

Part A and Part B

- If you successfully complete this study, the total amount you will be paid will be up to $1475.00 ($1175.00 plus $300.00 completion bonus)
- 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 will be reduced
- If you choose to leave or are withdrawn from the study before finishing all visits, your payment will be based on how much of the study you completed
  - This pay will be based on $175.00 for each overnight stay (3), $250.00 for each follow-up visit to the clinic (1 is planned), and $100.00 per week for the time between the last dose of study drug and the follow-up phone call (4 weeks)
- Partial payments are planned during the study. Details will be provided at screening
- A final payment will be provided to you about 2 weeks after you finish the study

Back-up Participants:

- If you are a back-up participant who is required to stay in the CRU overnight, you will be paid $250.00 per night that you stay
- If you are not required to stay overnight, you will be paid $190.00

You will be paid a prorated amount based on the extent of your participation if:

- You are not able to complete the study

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- 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

YOUR DECISION TO BE IN THE STUDY

Whether you are in this study is entirely up to you. You cannot be forced to be in this study. You may not want 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 clinic for a final visit. You may have some end of study evaluations or tests at this visit. This is to ensure your safe exit from the study. Also, 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 by contacting 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

ADDITIONAL COSTS

There will be no charge to you for taking part in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

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

By checking each of the following, you are agreeing that the statements below are true:

		Please Check
A.	This consent form is written in a language I understand.	
B.	I understand the information in this consent form.	
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 think 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 healthcare.	
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 can't 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 FORM.

- You will get a copy of this signed and dated Informed Consent Document 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 Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name or Initials of Person Explaining Informed Consent

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

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
bgb/10-3-19 bgb/11-12-19

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ADDITIONAL CONSENT REQUEST

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.

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.

Biological samples will be handled in a manner that protects your privacy and confidentiality. Biological samples will be assigned your study identification code (ID) at the site. The data generated from these biological samples will also be labeled with this ID. The key between your ID and your direct personally identifying information (for example, name, address) will be held at the study site.

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

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9. Contact Information

The study team 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 team or wish to speak with someone not involved with the Additional Research.

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 those purposes described above.

OR

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

11. 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 Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name or Initials of Person Explaining Informed Consent

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