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INTEGREVIEW IRB
DECEMBER 15, 2020

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Pfizer Inc
NUMBER AND NAME OF STUDY:	B7981054; "A PHASE 1, 2-PERIOD, FIXED-SEQUENCE, MULTIPLE-DOSE, OPEN-LABEL STUDY TO ESTIMATE THE EFFECTS OF RITLECITINIB (PF-06651600) ON THE PHARMACOKINETICS OF A SINGLE DOSE OF CAFFEINE IN HEALTHY PARTICIPANTS"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY INVESTIGATOR):	Mona Shahbazi, 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

Ritlecitinib (PF-06651600) will be referred to as the "study drug" in the rest of this consent document.

The purposes of this study are:

- To compare how much caffeine is in your blood when you take only caffeine and when you take caffeine after taking more than one dose of study drug.
- To see how a new drug is tolerated, if there are significant side effects, and how healthy adult people feel after it is given in combination with caffeine

The study drug is an investigational drug being studied to treat people with inflammatory conditions and diseases. This includes:

- Alopecia areata (bald patches) (AA)
- Rheumatoid Arthritis (RA)
- Vitiligo (loss of skin pigment)
- Inflammatory Bowel Disease
  - Ulcerative Colitis (UC)
  - Crohn's Disease (CD)

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
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"Investigational" means that the drug has not been approved by the United States (U.S.) Food and Drug Administration (FDA).

Caffeine will also be given in this study. Caffeine is an approved marketed, mild central nervous system stimulant. The use of caffeine in this research study is investigational.

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.

ABOUT THE STUDY

Number of Study Participants

There will be about 12 people taking part in this study.

Length of Study for Participants

You will be in this study for about 42 days. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

- 2 dosing periods during 1 continuous admission
- 13 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

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.

Dosing Plan

The dose of the study drug that will be used to treat people is not yet known. The dose in this study will be 200 mg, given as four 50 mg tablets.

Caffeine will also be given in this study. Single doses of caffeine of up to 200 mg have been given to healthy adults with no safety concerns. The dose given in this study will be 100 mg, given as tablets. This is about as much caffeine as a cup of coffee.

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The study has 2 periods. Dosing is planned as follows:

NUMBER OF PARTICIPANTS	STUDY PERIOD	DOSING			
		STUDY DAYS			
		1	1-7	8	9
12	1	100 mg caffeine			
	2		200 mg study drug once each day	200 mg study drug + 100 mg caffeine	200 mg study drug

Each dose will be taken with about 8 oz. of water. In Period 2, you may receive an extra 100 mL of water if needed. The dose must be swallowed whole. We will check your mouth to make sure the tablets have been swallowed.

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, vitamins, dietary supplements, or herbal supplements taken in the past 28 days
- Height and weight will be measured
- Vital signs (blood pressure, heart rate, and oral temperature) will be measured
- An electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- Safety lab tests will be done from blood and urine samples. In addition:
  - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
  - Blood test for tuberculosis (TB)
    - Positive results for TB may have to be reported to the State Department of Health
  - Urine to test for drugs of abuse (illegal and prescription) and cotinine (by-product of nicotine)
  - Females able to have children will have a blood pregnancy test
  - 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

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- 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
- A complete physical exam. This may be done at screening or when you check-in for the study
- You will be asked "How do you feel?"
- The proper use of birth control will be reviewed

HIV and Hepatitis Testing

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

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

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

Having certain infections or positive test results may have to be reported to the State Department of Health. This includes results for HIV, hepatitis, and other infections. If you have any questions about what information is required to be reported, please ask the study investigator or study staff.

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

During the Study

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

- You will be asked about any updates to your medical history
  - This includes medication, drug, alcohol, and tobacco use
- Physical exam
- The use of proper birth control will be confirmed/reviewed
- Vital signs will be measured.
- You will be swabbed for COVID-19
- You will be asked "How do you feel?" each day
- The study investigator may decide to do an alcohol breath test at any time
- An intravenous (IV) catheter may be placed in a vein in one of your arms for blood collection
- Blood and urine samples will be collected at various times throughout the study
  - The blood and urine samples will be used for safety labs
  - Urine samples to test for drugs of abuse and cotinine
  - 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

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  - Blood samples will also be used to measure the levels of caffeine, study drug, and study drug by-products 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 for the following:
      - Exploratory analysis
      - Check the laboratory test which measures the study drug and caffeine
- 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)
- You will receive a follow-up phone call about 4 weeks after the last dose of study drug
- For safety reasons, we may add procedures at any time during the study to check on your health status

Blood Draws

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

There will be about 44 blood draws. The total amount of blood drawn during the study will be about 200 mL. This is equal to about 7 oz., or a little more than ¾ of a 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, rest and good eating habits are recommended.

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

Frequently Reported Negative Effects

The study drug has been studied in the following:

- Healthy participants (in single doses up to 800 mg and multiple doses up to 400 mg daily for 14 days)
- Patients with RA (at the dose of 200 mg daily for 8 weeks)
- Patients with AA (at a starting dose of 200 mg daily for 4 weeks, followed by a maintenance dosing of 50 mg daily)

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In all those studies (156 people total), the study drug was generally safe and well tolerated. There are also ongoing studies of the study drug in patients with UC, CD, AA, and vitiligo.

The negative effects that were reported in more than 5% (1 in 20) of 48 patients with AA receiving the study drug for up to 24 weeks were:

- Headache
- Infections of the upper respiratory tract
- Acne
- Diarrhea
- Nausea
- Skin infections

Reactivation of Viruses

Certain viruses can stay in the body without causing symptoms. These viruses can reactivate (wake up) and cause disease. In studies with the study drug or other similar medications, reactivation of the chicken pox virus (herpes zoster) has caused shingles (a skin condition with blisters with burning or pain which may last after the rash clears). Reactivation of the herpes simplex virus has caused cold sores or fever blisters in the mouth or genital ulcers. We don't know if the study drug could lead to the reactivation of hepatitis viruses. You will not be allowed to be in the study if your blood tests show that you have had hepatitis types B or C viruses. You will not be allowed to be in the study if you have had more than one episode of shingles or if you have ever had even a single episode of shingles or herpes virus infection that spread inside your body or widely over your skin. During the study, call your study investigator right away if you think you may have:

- Shingles
- Ulcers in the genital area
- Cold sores

Serious or Unusual Infections

The study drug is a drug that affects your immune system. It can lower the ability of your body to fight infections. This can lead to more serious infections or infections that usually don't occur in people with a normal immune system. Some people have had serious infections or unusual infections while taking the study drug or other similar medications. You will not be allowed to be in the study if you have any kind of infection. Tell the study investigator if you have any symptoms of an infection. Symptoms of an infection could include:

- Fever
- Weight loss
- Excessive tiredness
- Other symptoms specific to the site of infection, such as a persistent (continuing) cough

You will be discontinued from the study if you have a serious infection. The study drug can make you more likely to get infections or make any infection that you may already have worse.

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Cancer

The study drug may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphoma (a type of blood cancer) and other cancers, including skin cancers, have been reported in patients taking medications that work in a similar way to the study drug. Most people with a history of cancer will not be eligible for this study, except for those who have had:

- Successfully treated skin cancers that were not the melanoma type
- Successfully treated local cancer of the cervix (the lower part of the uterus)

Tell the study investigator if you have had any type of cancer.

Changes in Certain Laboratory Test Results

Your blood will be tested before you start taking the study drug and at the end of Period 2 before you are discharged. Some changes in blood tests that have occurred in earlier studies with the study drug are described below. The investigator might do additional tests if needed and you might be discontinued from the study if certain blood tests change to a level which would cause concern for your continued participation in the study.

- Decreases in lymphocyte counts. Lymphocytes are white blood cells that help the body fight off infections. If your lymphocytes are low, you might be more likely to get an infection
- Changes in neutrophil counts. Neutrophils are white blood cells that help the body fight off infections. If your neutrophils are low, you might be more likely to get an infection
- Decreases in platelet counts. Platelets are blood cells that help blood to clot. If your platelets are low, you might be more likely to bruise or bleed. Although bleeding or bruising related to low platelets has not been seen in previous studies with the study drug, there is still a potential risk that this could happen
- Changes in other laboratory tests, such as your blood cholesterol or hemoglobin (red blood cells) levels, may also be seen

Skin Effects

Rash and acne have been seen in studies with the study drug. The majority of events were reported as mild. It is not known if the study drug causes these skin effects. During the study, you should tell the study investigator if you notice any changes on your skin**.** A referral may be made to a specialist who may take a skin biopsy (a small sample of skin that is cut and removed) to investigate a rash. Photographs of a rash may also be taken.

Other Effects

Studies have been done in animals to identify risks that may occur in people that are given the study drug. In studies with dogs, changes in the nervous system related to the study drug were seen after 9 months of taking doses more than 6.5 times higher than the 50 mg clinical dose. After 7 months, at even higher doses (more than 12 times higher than the 50 mg clinical dose), a few dogs had hearing loss. All the changes in the nervous system and hearing loss got better after stopping the study drug. Because the dog findings happened only at doses much higher than will be used in this study, it is unlikely that there are related human risks from the study drug at the dose used in this study.

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You may be referred for additional evaluation by a doctor specializing in diseases of the nervous system (if necessary).

Medications that work in a similar way to the study drug may increase the risk of developing blood clots in your legs (deep vein thrombosis) or lungs (pulmonary embolism).

The study drug is investigational. All of its side effects are not known. There may be rare and unknown side effects. This includes 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.

Caffeine Risks

Too much caffeine may cause:

- Nervousness
- Irritability
- Sleeplessness
- Occasionally, rapid heartbeat

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

Other Risks

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

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations (racing heart)

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- Chest discomfort/tightness
- Muscle pains/stiffness

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

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain

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

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

Additional Risks or Discomforts

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

Genes are pieces of DNA that, 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.

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.

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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 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
- Redness of the vein
- Pain
- Nerve damage

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

ECG

Possible side effects from having an ECG 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.

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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 drugs in the last 7 days or any previous history of nasal surgery.

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

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 doctor or study staff.

Other

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

Use of Birth Control

Females unable to have children

Women in this study 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, during the study, and for at least 28 days after the last dose of study drug.

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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)

- Non-hormonal intrauterine device (IUD)
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has had a vasectomy (absence of sperm confirmed)

User dependent methods (methods that rely on you to remember to use them)

- Sexual abstinence - defined as refraining from heterosexual intercourse and is the preferred and usual lifestyle of the participant

Males

Male participants are not required to use birth control during the study.

Pregnancy-Related Risks

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

- Sperm
- Pregnancy
- Unborn child
- Breastfeeding child

In animals, the study drug was linked with fetal changes in bones and some internal organs, and lower fetal body weight. Because of this and the investigational nature of the study drug, it should not be administered to pregnant women or fertile women of childbearing potential who are unwilling or unable to use the required contraception for this study.

When the study drug was given to healthy women together with oral birth control containing the hormone estradiol, the level of estradiol in the blood was decreased. The clinical significance of this decrease is not known. However, this may decrease the effectiveness of estrogen-containing birth control. If you are a woman able to have children, acceptable methods of birth control are detailed in the section above.

When male rats were treated with the study drug and then mated with female rats that were not treated, there were smaller litter sizes due to fewer fertilized eggs attaching to the wall of the uterus in those female rats. There were no effects on sperm or features of male reproduction.

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 procedures 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. It is not known whether the study drug is secreted into human milk. Because of this and the investigational nature of the study drug, it should not be administered to breastfeeding women. If you are a man whose partner is currently pregnant or plan to father a child, you should not join this study.

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

Pregnancy Follow-Up

Birth control methods, even when used consistently and correctly, are not perfect. If you or your partner become 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/your partner or your pregnancy doctor is 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, you must call the CRU at the 24-hour phone number listed on the first page of this consent form 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 hormone replacement therapy (HRT) or 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
- You may not take any medications that inhibit or induce CYP1A2 within 28 days before the first dose.
  - The study investigator or study staff will review these types of medications with you during the screening process
- You must not take any investigational drugs within 30 days before the first dose of this study
- You must not have been vaccinated with a live or attenuated (weakened) vaccine or any live viral components within 6 weeks of the first dose and for 6 weeks after the last dose
  - You should avoid any routine household contact with individuals who have received a live vaccine during the study and for 6 weeks after the last dose

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- 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
- 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. of 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 within 3 months before your first dose of study drug. 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
- 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 14 days 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 dosing, unless needed for any study procedures

Diet Restrictions

- On the days you will be dosed with caffeine, you must not eat or drink anything for at least 10 hours before each dose and for 4 hours after dosing
- You must not eat or drink anything for at least 8 hours before collection of the pre-dose blood sample for study drug. Water is allowed during this time
- You must not eat or drink anything for at least 4 hours before each safety laboratory test. Water is allowed during this time
- 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

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- You must not eat or drink anything with alcohol for 72 hours (or as stated above for red wine) before check-in. Alcohol is not allowed through the collection of the last blood sample for study drug in Period 2
  - 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 7 days before dosing. Caffeine is not allowed through the collection of the last blood sample for study drug in Period 2
  - 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 with chocolate or chocolate-containing products within 7 days prior to the first dose
  - Chocolate can be found in different foods and drinks. Some examples include hot chocolate, ice cream, and cookies
- You must not eat charcoal-broiled beef within 7 days prior to the first dose
- You must not eat cruciferous vegetables within 7 days prior to the first dose
  - Some examples of cruciferous vegetables are cauliflower, broccoli, brussel sprouts, and cabbage
- 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, HIV status, and TB status
- **Data from testing and analysis of biological samples** (such as blood or urine) **and images.** This may also include genetic information

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- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet. This information may include:
  - The length of time it takes you to complete the consent process
  - The number of times you scroll between pages or click on the hyperlinked items
  - Your electronic signature

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

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

Your personal information will be accessed by:

- The study investigator and other study staff members
- Pfizer and its representatives (including its affiliated companies)
- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. FDA and authorities in other countries)
- 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.

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

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

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

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

How are my biological samples handled?

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

Can my coded information 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

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To help avoid injury, it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.

You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. A 24-hour answering service is available.

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

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

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

Legal Rights

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

Contact Information

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

Mona Shahbazi, 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

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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 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 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

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 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 is not 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 or cotinine, 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

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Screening Payments

The screening payment 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).

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

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		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay	$190.00	13
Time Between discharge and Follow-Up Phone Call	$100.00	4 weeks
Completion Bonus	$780.00	
Total Payment	$3650.00	

BACK-UP PARTICIPANTS	
Type of Activity	**Payment**
Overnight Stay (per night)	$250.00
Daytime Stay	$190.00

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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.

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 and is not limited to the disease or condition that is the focus of the study.

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