INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

Sponsor / Study Title:	**Pfizer Inc / "A PHASE 1, RANDOMIZED, DOUBLE-BLIND, SPONSOR OPEN, PLACEBO-CONTROLLED, DOSE ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE AND MULTIPLE INTRAVENOUS AND SUBCUTANEOUS DOSES OF PF-07275315 IN HEALTHY PARTICIPANTS"** **Part A - SINGLE DOSE**
Protocol Number:	**C4531001**
Principal Investigator:	**Sylvester Pawlak, APRN**
Telephone 24 Hours:	**203-401-0300**
Address:	**New Haven Clinical Research Unit** **One Howe St** **New Haven, CT 06511**

1.1.1. 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.

2. PURPOSES OF THE STUDY

PF-07275315 will be referred to as the "study drug" in the rest of this consent document.

This consent document is limited to describing only those procedures and dosing in Part A (Single Dose) of the study that you may undergo if you qualify for the study.

The purposes of this study are:

- To see how a new drug under study is tolerated, if there are significant side effects, and how people feel after receiving single or multiple doses
- To measure the amount of study drug in your blood after single or multiple doses
- To evaluate the immunogenicity profile of the study drug after single and multiple doses in healthy adults
    - The immunogenicity profile will measure if your body develops antibodies (an immune response) after dosing with the study drug
- To evaluate the effects of the study drug on exploratory biomarkers
- Biomarkers are natural substances in your body that can be used to show how your body works

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

The study drug is an investigational drug being studied to treat people with atopic dermatitis (AD). AD is a form of eczema (itchy, inflamed skin rash). "Investigational" means that the drug has not been approved by the United States (U.S.) Food and Drug Administration (FDA). Study drug and placebo will be given as an intravenous (IV) infusion, through a small tube placed in a vein in one of your arms.

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

ABOUT THE STUDY

Number of Study Participants

There will be about 53 participants taking part in this part of the study. This study is being done at about **4** different study sites in 2 countries. It is expected that about 11 people will take part in this part of the study at this location.

This research study may use competitive enrollment. This means that when a certain number of people have entered the research study from all research sites combined, no one else will be allowed to participate. It is possible that you may not be allowed to join the research study.

Length of Study for Participants

If you are in Groups 1 or 2, you will be in this study for about 271 days.

If you are in Groups 3 through 8, or group 12 (optional, may not be done), you will be in this study for about 541 days.

The length of study does not include the time between screening and dosing, which can be up to 28 days.

Additional follow-up visits, at up to 3-month intervals, up to a maximum of 12 months, after the last planned follow-up visit, may be needed depending on the study results.

The number of follow-up visits/duration of study participation may be decreased depending on the study data from earlier groups.

This study involves:

Groups 1 and 2

- 1 dosing period
- 5 overnight stays at the Clinical Research Unit (CRU). You will not be able to leave the CRU during that time
- 8 planned follow-up visits

Groups 3 – 8, and 12 (if done)

- 1 dosing period
- 5 overnight stays at the CRU. You will not be able to leave the CRU during that time
- 11 planned follow-up visits

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 you are discharged from the study. If the study drug stays in your body longer, or you are having an immune response, you may need to wait as long as 6 to 8 months, or longer, before you can screen for another study. These results are usually known after your last regularly scheduled 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.

Up to 9 groups of participants are planned for this part of the study.

Dosing in Part A of the study is planned as follows:

GROUP NUMBER	NUMBER OF PARTICIPANTS	STUDY DAY 1
1	4	0.3 mg study drug or placebo
2	4	1 mg study drug or placebo
3	4	3 mg study drug or placebo
4	6	10 mg study drug or placebo
5	6	30 mg study drug or placebo
6	8	100 mg study drug or placebo
7	8	300 mg study drug or placebo
8	8	1,000 mg study drug or placebo
12*	5	TBD# mg study drug or placebo

*Optional group

#TBD – to be determined (based on information from the previous groups in this part of the study).

The number of participants in Groups 1 – 3 may be increased by four (2 more on active study drug and 2 more on placebo) depending on results from the original 4 participants in these groups.

Doses in this part of the study may be adjusted depending on the study drug levels in the blood of participants in the previous group. Doses may be repeated. Other doses may be explored in additional groups of participants.

Study drug and placebo will be given by an infusion in one of your arms. Infusion time will be about 60 minutes.

If you experience symptoms during study drug infusion, the study investigator may decide to temporarily stop the infusion, restart at a slower rate, or discontinue the infusion permanently.

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

It will be randomly assigned, like the flip of a coin, who receives either the study drug or placebo.

- You have about a 1 in 2 chance of receiving placebo during the study if you are in Groups 1, 2 or 3
- You have about a 1 in 3 chance of receiving placebo if you are in Groups 4 or 5
- You have about a 1 in 4 chance of receiving placebo if you are in Groups 6, 7, or 8
- You have about a 1 in 5 chance of receiving placebo if you are in Group 12 (if done)

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

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

Study Process

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

Screening

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

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

- Give your race, age, gender, and ethnicity
- Give your medical history
  - You must review and confirm the information in your medical history questionnaire
- Give your drug, alcohol, and tobacco use history
- Give your past and current medication and treatment history. This includes any over-the-counter or prescription drugs, such as vitamins, dietary supplements, or herbal supplements, taken in the past 28 days
- Height and weight will be measured
- Physical exam. This may be done at screening or when you check-in for the study
- Vital signs (blood pressure, heart rate, breathing rate, and oral [by mouth] temperature) will be measured
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- Complete a COVID-19 questionnaire

- All participants may be tested for COVID-19 at each visit to the CRU
  - Study 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
- Safety lab tests will be done from blood and urine samples. In addition:
  - Blood tests for aPTT and PT-INR (tests of your blood's ability to clot)
  - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
  - Blood tests 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)
  - 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
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed
- You will be asked "How do you feel?"

HIV and Hepatitis Testing

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

HIV is the virus that causes acquired 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 prior diseases, medication, drug, alcohol, and tobacco use
- Physical exam, including eye exam
- Weight will be measured

- The use of proper birth control will be confirmed/reviewed
- Vital signs will be measured. Your oral temperature will also be measured
- ECGs will be collected
    - It may be necessary to shave or trim hair on your chest so that the patches for the ECGs will stick to your skin
    - Your chest may be marked with a pen to identify the correct areas for ECG patch placement
- Continuous heart monitoring will be done for at least 6 hours after dosing. There will also be a period of at least 2 hours where monitoring will be done before dosing
    - This involves the attachment of a small box like unit (transmitter) to your chest
    - The box is attached by a few wires (similar to those of an ECG)
    - The monitor sends information about your heart's activity by a radio signal to a monitor
    - You may not sleep during the 2 hours of continuous monitoring done before dosing
    - You will need to stay in the procedure room for at least 4 hours after dosing while attached to the monitor
    - You will need to keep the box with you during the monitoring period
    - You will be asked to minimize activity while attached to the monitor
- You will be asked: "How do you feel?" each day
- An IV catheter will be placed in a vein in one of your arms for study drug or placebo administration. A second IV may be placed in the opposite arm for blood collection or safety reasons
- The study investigator may decide to do an alcohol breath test at any time
- You will complete a COVID-19 questionnaire
- You will be swabbed for COVID-19
- Blood and urine samples will be collected at various times throughout the study
    - Safety Labs: The blood and urine samples will be used for safety labs including the following:
        - Blood samples for aPTT and PT-INR
        - Urine samples to test for drugs of abuse
        - blood samples for pregnancy testing (females able to have children). Pregnancy tests may be performed at the discretion of the study investigator in all females

    - Any leftover serum (component of blood) from the safety lab samples may be stored and used to assess exploratory biomarkers or unexpected safety findings
        - Samples used for this purpose will be kept for up to 1 year following completion of this study

- Study Drug Levels: Blood samples will also be used to measure the levels of study drug
    - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for the following:
        - Metabolite identification (by-products or end products of a drug produced as the body processes a drug)
        - Evaluate safety or efficacy (ability to produce a desired effect) aspects related to any concerns during or after the study
        - Check the laboratory test which measures the study drug
        - Other internal exploratory purposes
- Biomarkers: Blood samples will also be used to measure a number of specific biomarkers related to the body's immune system and AD or other inflammatory skin conditions for exploratory purposes
- Retained Research Samples: Samples of your blood will be collected, stored, and used to learn more about the study drug and AD or other inflammatory skin conditions
    - Biological substances in your samples, including your genes, may be studied
    - These samples may be kept by Pfizer for as long as the samples are useful for scientific research. This may be for many years (no time limit)
- Immunogenicity: Blood samples will also be used to measure your immune system response to the study drug:
    - Anti-drug antibody (ADA)
    - Neutralizing antibody (NAb)
    - Samples may also be used for the following:
        - Additional evaluation of the immune response
        - Check the laboratory tests which measure the immune response
        - Other exploratory purposes
- Your infusion site will be checked for any reactions

You will return to the CRU for follow-up visits after the last dose of study drug or placebo as follows:

- Days 8, 15, 32, 46, 61, 91, 181, and 271 - Groups 1 and 2
- Days 8, 15, 32, 46, 61, 91, 181, 271, 361, 451, and 541 – Groups 3 – 8 and 12

For safety reasons, we may add procedures at any time during the study to check on your health status, or additional follow-up visits beyond those scheduled (as detailed above)

Follow-ups may be done using telehealth visits (by phone or zoom) and/or home health visits (health care provider comes to you)

Blood Draws

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

There will be up to about 22 blood draws. The total amount of blood drawn during the study will be about 770 mL. This is equal to about 26 oz (about 3 ¼ cups). For comparison, the standard blood donation is about 16 oz. (2 cups), once in any 56-day period.

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

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

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

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug 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

The study drug is a new type of antibody. An antibody is a protein that the body uses to fight infection. It targets 3 proteins, known as cytokines, that are believed to be important in causing the inflammation seen in skin diseases such as AD (eczema) and related diseases. inhibition (restricting) of these cytokines alone have been shown to be safe and well tolerated in humans and to have benefit in treating AD and /or asthma. However, the safety and effectiveness of inhibiting all 3 cytokines at the same time have not been studied in people.

The study drug has never been given to people before. Therefore, the safety, toleration, and side effects in humans are not known. Studies have been done in animals to identify the risks that may occur in people given the study drug.

The study drug has been tested in monkeys for months to see if it would likely be safe to give to people and to identify any possible undesirable side effects. No side effects were identified in this study even at the highest dose tested that produced levels of the study drug in the blood over 10 times the maximum predicted blood levels planned in human clinical trials. Animal studies cannot entirely predict symptoms that may arise after administration of the study drug. There may be rare and unknown side effects, including reactions that may be life-threatening.

Based on a test in which blood cells were exposed to the study drug in a test tube (that is, outside of the body), the study drug may have a low risk of causing release of certain proteins (known as cytokines) that could result in a condition known as cytokine release syndrome (CRS). CRS is a serious condition that could result in the need for hospitalization. CRS is easily monitored in the clinic. Other studies have shown that the study drug has a low risk of binding to proteins (known as complement) that start a process normally used by the body to fight infection and destroy germs. If this process is started when there is no infection, there is a risk that the proteins will attack normal cells. To minimize the possible risks of CRS and complement binding, we are only giving the study drug to people in a controlled clinical setting in early clinical studies. Dosing in this first clinical trial will start at a very low dose level. Doses in this first study will be increased gradually and only if the lower dose is well-tolerated.

The study drug can cause the body to form antibodies (proteins in the blood that identify and help destroy invaders, like bacteria) to the drug. Any foreign protein (including any other antibody drug) can cause these antibodies to form. this is not specific to the study drug. These antibodies could affect the potential for you to be treated successfully with the study drug or similar drugs in the future. It may also increase your likelihood of becoming allergic to the study drug or similar drugs in the future. The study drug may also cause reactions at the site of the injection.

The studies in animals did not show that the study drug can cause any problems with the eyes, but other drugs, that work in the similar way to this study drug showed a small risk of "conjunctivitis". Conjunctivitis is known as 'pinkeye', which is an inflammation of the eye and the inside of the eyelid that can cause redness, irritation, itching, and watery eyes. During the study, your study Investigator will examine your eyes for signs of

conjunctivitis, and you should inform your study staff if you notice any changes to your eyes. You will be referred to an eye specialist (Ophthalmologist) if you develop conjunctivitis.

The study drug has not been tested in animals to see if it can cause or increase the risk for cancer. However, antibody drugs like the study drug generally have a low risk for causing cancer.

All drugs that reduce inflammation may increase the risk of infection. The cytokines targeted by the study drug are involved in fighting infections with parasites, like worms (helminths). Other drugs that work like the study drug generally have a low risk of infection. However, until more human data are available, participants in early clinical trials should try to avoid travel to areas where parasites like worms are common.

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

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

All drugs have a potential risk of an allergic reaction. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help (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)
- 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(s) may be given as needed for your safety
- Depending on how severe your symptoms are, you may be seen by outside medical providers or a hospital. This would be for further evaluation and/or treatment
- The study investigator may notify your emergency contact as appropriate in the event of an emergency while you are taking part in the study

Additional Risks or Discomforts

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

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

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

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

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

- Life insurance
- Long term care insurance
- Disability insurance

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

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

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

Blood Samples and IV Catheters (if used)

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

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

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

COVID-19 Testing

Collection of a swab sample may cause:

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

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

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

If you test positive for COVID-19 you cannot be in the study. If you have a positive result, it will be reported to the State Department of Health. If you have any questions about what information must be reported, please ask the study investigator or study staff.

ECG and Continuous Heart Monitoring

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

- Irritation or rash from the adhesive on the patches

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

Fasting

Fasting could cause symptoms such as:

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

Other

The length of time that you will be in this study may be challenging to your personal schedule.

Use of Birth Control

Females unable to have children

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

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

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

Females able to have children

If you are sexually active, you must use a highly effective method of birth control. The birth control must be used consistently and correctly from the start of dosing (earlier for hormonal birth control), during the study, and for at least 450 days after the last dose of study drug.

Highly effective methods of birth control include:

- Implantable progestogen-only hormone birth control
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has a vasectomy (absence of sperm confirmed)
- Hormonal birth control* **(See Note below)**
- Sexual abstinence – defined as refraining from heterosexual intercourse during the study and until you are discharged from the study, and is the preferred and usual lifestyle of the participant

PLUS

***Note:** One of the following barrier methods must be used in addition to the use of **hormonal birth control methods**:

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

Males

No birth control methods are required for male participants in this study.

Pregnancy-Related Risks

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

- Fertility
- Pregnancy
- Unborn child
- Breastfeeding child

At this time, it is not known whether the study drug can cause harm to an unborn child when given to pregnant women. Animal reproductive studies have not been done with the study drug. It is also not known whether the study drug can affect the ability of males or females to have children, or if the study drug is secreted in human milk. For this reason, pregnant or nursing women cannot take part in early clinical studies with the study drug. Women who are able to have children will need to use appropriate birth control to prevent pregnancy and will be monitored for pregnancy during early clinical trials.

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

If you are currently pregnant, plan to become pregnant, or are breastfeeding 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

If you or your partner become pregnant within 450 days after your last dose of study drug or before the study completion, please:

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

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

PARTICIPANT RESPONSIBILITIES AND RIGHTS

PARTICIPANT RESPONSIBILITIES

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and diet and activity restrictions (details listed later in this document)
- You must not take any prescription medications within 7 days before the first dose or at any time during the study
  - Limited use of nonprescription medications may be allowed on a case-by-case basis
- You should refrain from starting new or changing doses of non-prescription medications, vitamins, and dietary supplements within 7 days before the first dose or at any time during the study
    - Hormonal methods of birth control are allowed
    - Before taking any drugs other than the study drug, you must call the CRU for approval. It must first be approved by the study investigator
    - You must tell the study staff about any drugs taken during the study
    - You must tell the study staff about any changes to permitted medications during the study as soon as they occur

- You must not take any investigational drugs within 30 days before the first dose of this study
- You must not have a history of either untreated or inadequately treated latent (infection is present but not active) or active TB infection
- You must not have received the COVID-19 vaccine within 7 days before screening or admission to the CRU or be scheduled to be vaccinated at any time while confined to the CRU for the study
- You must not have any of the following acute (comes on suddenly and lasts a short time) or chronic (keeps returning and lasts a long time) infections or history of infection
    - Any infection requiring treatment within 2 weeks before the screening visit
    - Any infection requiring hospitalization or IV antimicrobial therapy within 60 days of the first dose
    - Any parasitic infection requiring treatment within 2 weeks of the screening visit
    - Any infection judged to be opportunistic (occurs because of a weakened immune system) or clinically significant by the study investigator within 6 months of the first dose
    - Known active or history of recurrent bacterial, viral, fungal, mycobacterial, or other infections
    - History of recurrent (more than one episode) localized (affects a limited area) of herpes zoster (shingles) or history of disseminated (widely spread) (one single episode) herpes simplex (mouth or genital sores) or disseminated herpes zoster
- You must not have a history of travel to a region with endemic (disease or condition regularly found in a certain area) parasite infection as judged by the study investigator
- You must not have had a fever within 5 days of the first dose
- You must not have been exposed to a live or attenuated (inactive) vaccine within 28 days of the screening visit
- You must not have any cancers or a history of cancer with the exception of adequately treated or excised (removed) non-cancerous basal or squamous cell skin cancer or cervical cancer that has not spread

- You must not have a history of any lymphoproliferative disorders (diseases with uncontrolled production of lymphocytes [a type of white blood cell]) such as Epstein Barr Virus (EBV – causes mononucleosis) related lymphoproliferative disorder, history of lymphoma (cancer of the lymphatic system), history of leukemia (blood cancer) or signs and symptoms suggestive of current lymphatic or lymphoid disease

- You must not have undergone significant trauma or major surgery within 1 month of the first dose

- 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 may donate about one pint every 3 months, 3 months after the last dose

- 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 use tobacco or nicotine containing products in excess of the equivalent of 5 cigarettes per day or have been smoking a pack a day for greater than or equal to 10 years

- You must not be using/taking any drugs of abuse (such as marijuana, cocaine, opioids, etc.). Urine tests may 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 study 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 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 5 days in a row 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 (each) dosing unless needed for any study procedures
- You will be confined to the procedure room for the first 4 hours after dosing during continuous cardiac monitoring, except to use the bathroom
- You must not use tobacco- or nicotine-containing products, including vaping, for 24 hours before check-in and each outpatient visit, and while confined to the CRU

Diet Restrictions

- You must not eat or drink anything (except water) for at least 4 hours before each safety lab test
- You may drink water freely
- You must not eat or drink anything with alcohol for 24 hours before check-in, before each outpatient visit, and while in the CRU
    - Study staff may check your breath for alcohol. If alcohol is found, you will not be allowed in the study
- You must not eat or drink anything with caffeine for 24 hours before check-in and each outpatient visit
    - Caffeine can be found in different foods and drinks. Some examples include chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- Breakfast will be provided before dosing
- Lunch will be provided about 4 hours after dosing

- Dinner will be provided about 9 – 10 hours after dosing
- An evening snack may be permitted on each dosing day
- Meals (breakfast, lunch, dinner, and evening snacks) will be provided at appropriate times on all other study days

2.1. 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

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

2.3. Confidentiality

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

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

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

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

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

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

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

- Emergency contact information
- Details of family medical history

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

Text Messages

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

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

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

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

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

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

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

Your Coded Information will be used by the following:

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

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

- **Conducting the study**, including:
  - Examining your response to the study drug

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

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

How are my biological samples handled?

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

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

Your Coded Information and biological samples may be used in other research projects to advance scientific research and public health. At this time, we do not know the specific details of these other research projects.

2.3.1.1.1.1.1.1.

Study-Related Injuries

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

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

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

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

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

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

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

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

2.3.1.1.1.1.1.2. Legal Rights

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

Whom to Contact About This Study

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

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;

- The study investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

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

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

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00061768.

Link to Additional Information

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

Payment for Taking Part in the Study

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

You may be eligible for a travel and hotel bonus payment:
$0.25/mile per one-way trip to or from the CRU based on your home address

- For participants traveling long distances, a 1-night hotel stipend ($150.00) for the night prior to your visit(s), if needed

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

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

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

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

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

Screening Payments

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

Screening Visit at CRU	$175.00

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

Study Payments

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

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

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

Groups 1 & 2

STUDY PARTICIPANTS		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$390.00	5 nights
Admission to Day 60	$15.00	60 days
Follow-Up beyond 60 days	$25.00	212 days
Follow-Up Visit to CRU	$500.00	8 visits
Total Payment	$12,150.00	

Groups 3 through 8, and 12 (if done)

STUDY PARTICIPANTS		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$390.00	5 nights
Admission to Day 60	$15.00	60 days
Follow-Up beyond 60 days	$25.00	482 days
Follow-Up Visit to CRU	$500.00	11 visits
Total Payment	$20,400.00	

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

*Overnight stay rates include an increase for COVID restriction inconveniences

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

If you have any unresolved events that may be related to having an immune response to the study drug you will be asked to stay on study for extended follow-up (beyond the last expected study visit day) and will return for follow-up visit(s) every 3 months. You will be compensated $2750.00 for every 90 days you remain on study.

2.4. Costs for Study Participants

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

Your Decision to be in the Study

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

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

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

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

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

2.5. New Findings

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

2.5.1.1.1.1.1. AGREEMENT TO BE IN THE STUDY
PIMS # _____

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

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

IF YOU DID NOT CHECK THE BOX NEXT TO ANY OF THE ABOVE QUESTIONS
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN AND DATE THIS CONSENT DOCUMENT

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

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

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

- You will get 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, if provided)

Signature of Adult Study Participant Date

Printed Name or Initials of **Person** Explaining Informed **Consent**

Signature of Person Explaining Informed Consent Date