INFORMED CONSENT AND AUTHORIZATION FORM

Sponsor / Study Title:	**Pfizer / A PHASE 2A, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, 16-WEEK STUDY EVALUATING THE SAFETY AND EFFICACY OF PF-06650833, PF-06700841 AND PF-06826647 IN ADULTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**
Protocol Number:	**C2501007**
Principal Investigator: (Study Doctor)	**Angela Y. Moore, M.D.**
Telephone:	**(817) 795-7546** **(214) 906-7027 (24 Hours)**
Address:	**Arlington Research Center, Inc.** **711 East Lamar Blvd, Suite 200** **Arlington, TX 76011**

Thank you for taking the time to consider joining this study. We understand that this may be a difficult decision. This consent document can help you make your decision by explaining **what you can expect to happen during this study**, also known as a clinical trial or a research study.

Your participation in this study is **completely voluntary (your choice)**. Take as long as you need to make your decision. You also can choose to take part in the study now, and then change your mind later at any time. Please keep in mind that even if you choose to participate, it may turn out that you do not meet the study's entry requirements.

We encourage you to **have conversations with your family, caregivers, doctors, and study team** about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

If you choose to participate in this study, **you will be asked to sign this consent document** prior to the study to let the study team know your decision.

In addition to this study, the study team will ask you to consider participating in **optional research. You will be asked to sign the additional consent documents** to let the study team know your decision. Participation is the optional research will be completely voluntary (your choice).

You will receive a signed copy of this consent document for your records. Please keep this consent document for your reference.

1. Key Study Information and Contact Information

The study team will address any questions, concerns or complaints you may have before, during and after you complete the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

Phone numbers for the study team are listed on page one of this consent form. **You also will be given a card with important emergency contact information, including a 24-hour number.** Show this card to any doctor, nurse or other health care provider if you seek emergency care while you are taking part in this study. This card includes information about the study that will help them treat you.

If you have any general questions about your rights as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly involved in the study, you may contact Advarra IRB.

2. Brief summary of this study

You are being asked to take part in a study that is sponsored by Pfizer (the "**Sponsor**"). The Sponsor is providing funding to the study doctor to conduct the study.

You are being asked to take part in this study because you are an adult that has moderate to severe Hidradenitis Suppurativa.

This study will explore the safety and response of the investigational product (study drug) on your hidradenitis suppurativa. This study is different from your regular medical care. The purpose of regular medical care is to improve or otherwise manage your health, but the purpose of research is to gather information to advance science and medicine and does not replace your regular medical care.

You will be asked to take part in the study for about 26 weeks, which includes up to a 6-week screening period, a16-week treatment period and a 4-week Follow-up period.

You will be assigned to receive one of the study drugs listed below, or a matching placebo (placebo does not contain any active ingredients):

- PF-06650833 (400 mg once a day) or matching placebo;
- PF-06700841 (45 mg once a day) or matching placebo;
- PF-06826647 (400 mg once a day) or matching placebo;

Each study drug and its matching placebo will look alike.

The study doctor will determine whether you are eligible for the study. If you join, you will receive one of the three study drugs listed above or a placebo (drug look alike

without any active ingredients). This study will require you to visit the study doctor at regular intervals (about every two weeks or monthly) as outlined in the table below to undergo study procedures and to provide information about your health.

You will be asked to provide biological samples (such as blood or urine) and undergo procedures that might be different from a regular medical examination. This study will involve physical exams, ECG, your completion of several questionnaires, clinical assessments of your disease, chest x-ray, tuberculosis testing, medical history and asking you about treatments, supplements and medications you are taking.

At certain selected sites, there may also be optional skin biopsies and photography of lesions (you will be required to sign and date a separate consent).

You may experience risks or discomforts when taking part in this study, which include some that are common such as pain, bruising, bleeding at the needle insertion site when a blood sample is taken. There are also risks that are unknown at this time. This is not a complete list of risks or discomforts. A more comprehensive list of risks and discomforts is provided later in this consent document.

It is possible that your condition or health may improve, worsen, or stay the same because you are taking part in this study. There is no guarantee that you will benefit in any way. However, your participation in this study may benefit future patients. Instead of taking part in this study, you may choose to receive treatment with other drugs that have been approved for use in this country. Taking part in this study is voluntary (your choice). There is no penalty or change to your regular medical care if you decide not to participate. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which you are entitled. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study.

You will receive a signed and dated copy of this consent document for your records. Please keep this consent document for your reference.

3. What is the purpose of this study?

You are being asked to take part in this study because you have moderate to severe Hidradenitis Suppurativa.

The purpose of this study is to learn about the effects of the study drugs, PF-06650833, or PF-06700841 or PF-06826647 and placebo to find out which is better for treating hidradenitis suppurativa. The study drugs PF-06650833, PF-06700841 and PF-06826647 are investigational drugs because they are not approved for use in this country by the United States Food and Drug Administration (FDA). 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 each of the three study drugs to see if there are any differences.

4. How long will I participate in this study?

You will be in this study for about 26 weeks. You will need to visit the study site about 10 times during the study. Once it is confirmed you are eligible for the study, you will receive your first dose of study drug or placebo at the baseline visit. The next visits will take place 1, 2, 4, 6, 8, 12 and 16 weeks after the first dose with a follow-up visit 20 weeks after the first dose.

5. How many people will take part in this study?

There will be about 192 people taking part in this study. The study is being done at about 60 different study sites in three countries.

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

6. What will happen during this study?

Before any study procedures begin, or before you begin preparing for the study, you will be asked to read, sign and date this consent document.

This consent document will be referred to as the main/core consent document.

In addition to this main study, the study team may ask you to participate in optional sub-study with skin sample collection with photography, as well as additional uses of your biological samples (for example, blood or urine). You will be asked to sign and date a Clinical Study Informed Consent for Biopsy and/or Photography and an Additional Optional Research Consent to let the study team know your decisions. Participation is completely voluntary (your choice). You may take part in the main study even if you do not want to take part in any optional uses.

Screening Visit

After signing and dating this consent document, the study will begin with a screening visit. The purpose of the screening visit is to find out if you meet all of the requirements to take part in this 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 doctor will explain why and will discuss other options that may be available to you.

Study Drug

If you participate in the study, you will be assigned by chance (like pulling a number out of a hat) to receive the one of the three study drugs or its matching placebo in a 3:1

ratio: PF-06650833; PF-06700841; PF-06826647, or a placebo. You will have a 75% (3 in 4) chance of receiving one of the study drugs, a 25% (1 in 4) chance of receiving the matching placebo.
Each study drug and its matching placebo will look alike, whether it is the placebo, or the active study drug. Due to the drug availability, you may have different chance to receive PF-6650833, PF-06700841, or PF-06826647 depends on the timing you enroll in the 16 weeks of the study treatment period. However, the chance of receiving study drug or placebo is still the same. No one (including you, your personal doctor and the study team) can choose the group you will be in.

This is a double-blind study, which means that you, your personal doctor and the study team will not know whether you are receiving the study drug, or the placebo. This is done to make sure that the study results cannot be unfairly influenced by anyone. In case of urgent need, the study doctor can learn quickly which drug you are receiving

PF-06650833/placebo will be supplied in a bottle and is to be taken by mouth once daily. PF-06700841/placebo will be supplied in a blister card and is to be taken by mouth once daily. PF-06826647/placebo is supplied in a bottle and is to be taken by mouth once daily. It is important you follow the exact dosing and storage directions provided by your study doctor. The study staff will instruct you on the proper storage requirements for take-home study drug.

You will swallow the tablet whole with room temperature water to a total volume of approximately 240 mL. It is important not to break, crush or chew the study drug prior to swallowing.

It is recommended that PF-06650833/placebo and PF-06700841/ placebo be taken while fasting; PF-06826647/placebo must be taken with food (immediately after a meal). On study drug dispensing study visit days, you are instructed to refrain from dosing at home, and are to take the dose in the clinic from your current blister card or bottle.

If a dose is missed and the time to the next dose is less than 8 hours, the missed dose should not be taken.

Your compliance with study drug will be assessed at each visit. It is important to bring all dispensed study drug supplies in the original packaging (used as well as unused) to every study visit.

You will be given the study drug in a bottle or blister package. If you think it will be hard for you to open or close this packaging, please tell the study team and other arrangements may be made. Please do not throw the study drug in the trash or flush it down the toilet. Do not give your study drug to any other person and keep the study drug out of the reach of children and those who cannot read the label. You will need to bring empty or partially used containers back to the study doctor at each visit.

Overview of Study Procedures and Assessments
You will have the following tests, procedures or assessments during this study.

In addition to the visits listed, the study doctor may ask you to come in for extra visits if necessary to protect your well-being and it may be possible to have additional blood work done, if needed. The total blood volume for individual participant will not exceed 550mL during any period of 60 consecutive days.

Screening Period:

Screening: (Site Visit time about 2.5 hrs.)

- You will have the study explained to you and have all your questions answered and decide if you want to participate in the study
- You will be asked about your medical history and any medications, treatments or supplements you may be taking or have taken; demography questions like age, gender.
- A full physical exam including listening to your heart and lungs; looking in your eyes, throat, ears, checking reflexes and your abdomen will be performed.
- Your blood pressure, temperature and pulse will be taken and your height and weight measured
- An ECG (tracings of your heart) will be done
- A chest radiograph will be done
- You will be asked to complete a questionnaire about if you are feeling sad or hurting yourself
- Blood samples will be taken (about 25 mL or 1.7 tablespoons) to check for safety, kidney function, viruses like HIV and Hepatitis, a pregnancy test for women who can have babies and for women age 60 and older a follicle stimulating hormone test
- A Tuberculosis skin test or assay will be done
- A urinalysis and urine drug screen will be performed
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be given a hand-held device to take home with you along with directions on how to use it to ***record daily your skin pain and disease symptoms*** from 7 days prior to your baseline visit throughout the entire duration of the study
- The study doctor will discuss contraception with you
- You will be asked how you feel
- Screening period can last from a day to 6 weeks

Treatment Period:

Baseline Visit: Day 1 (Visit will take about 2 hours at site)

- You will be asked about your medical history and any medications, treatments or supplements you may be taking or have taken; demography questions like age, gender.

- A full physical exam including listening to your heart and lungs; looking in your eyes, throat, ears, checking reflexes and your abdomen will be performed.
- Your blood pressure, temperature and pulse will be taken and your height and weight measured
- An ECG (tracings of your heart) will be done
- If it is determined you are eligible for the study, you will be given study drug and instructions on taking it
- A blood sample for fats (lipid panel) will be done at this visit and ***requires you to be fasting (water only) for at least 8 hrs. prior to site visit)***
- Blood samples will be taken (total blood volume take at this visit about 30 mL or 2.0 tablespoons) to check for safety, kidney function, banked biospecimen and blood for protein, RNA, TBNK, & exploratory analysis; drug concentration pre-dose will also be tested.
- A urinalysis will be done and urine pregnancy test for women who can have babies
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be given questionnaires about your disease severity, impression of change, quality of life and health survey
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 1 week later you will return to the study site for **Week 1, Day 8** (visit will take about 1.5 hrs.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken
- Blood samples will be taken (total blood volume take at this visit about 11mL or 0.7 tablespoons) to check for safety & kidney function; drug concentration pre-dose blood sample taken
- A urinalysis will be performed along with a urine pregnancy test for women who can have babies
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- **You will bring back your study drug in original container to the site**
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 1 week later you will return to the study site for **Week 2, Day 15** (visit will take about 1.5 hrs.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken

- Blood samples will be taken (total blood volume taken at this visit about 14.5mL or 1.0 tablespoon) to check for safety, kidney function and protein analysis
- A urinalysis will be performed along with a urine pregnancy test for women who can have babies
- Blood sample for study drug concentration will be taken before you take your study drug
- **You will bring back your study drug in original container to the site**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 2 weeks later you will return to the site for **Week 4 (Day 29)** (visit will take about 1.5 hrs.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken
- An ECG (tracings of your heart) will be done
- Blood samples will be taken (total blood volume take at this visit about 26mL or 1.8 tablespoons) to check for safety & kidney function, and blood for protein, RNA, TBNK, & exploratory analysis; drug concentration before you take your study drug
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site and have study drug given to you**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 2 weeks later you will return to the site for **Week 6 (Day 43)** (visit will take about 1.5 hrs.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken
- Blood samples will be taken (total blood volume taken at this visit about 11 mL or 0.7 tablespoon) to check for safety & kidney function along with a blood sample for study drug concentration before you take your study drug

- A urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 2 weeks later you will return to the site for **Week 8 (Day 57)** (visit will take about 4.5 hrs.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- You will be asked to complete a questionnaire about if you are feeling sad or hurting yourself
- Your blood pressure, temperature and pulse will be taken
- An ECG (tracings of your heart) will be done
- A blood sample for fats (lipid panel) will be done at this visit and ***requires you to be fasting (water only) for at least 8 hrs. prior to site visit)***
- Blood samples will be taken (total blood volume take at this visit about 38mL or 2.6 tablespoons) to check for safety & kidney function, and blood for protein, RNA, TBNK, & exploratory analysis; blood for study drug concentration before you take your study drug and one half hr., 1 hr., 2 hrs., and 4 hrs. after taking study drug
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site and have study drug given to you**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 4 weeks later you will return to the study site for **Week 12, Day 85** (visit should take about 1.5 hrs).

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken
- An ECG (tracings of your heart) will be done

- Blood samples will be taken (total blood volume take at this visit about 26mL or 1.8 tablespoons) to check for safety & kidney function, and blood for protein, RNA, TBNK, & exploratory analysis; blood for study drug concentration before you take your study drug
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site and have study drug given to you**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 4 weeks later you will return to the study site for **Week 16, Day 113** (visit should take about 1.5 hrs)

- A full physical exam including listening to your heart and lungs; looking in your eyes, throat, ears, checking reflexes and your abdomen will be performed
- Your blood pressure, temperature and pulse will be taken
- An ECG (tracings of your heart) will be done
- You will be asked to complete a questionnaire about if you are feeling sad or hurting yourself
- Your height and weight will be measured
- Blood samples will be taken (total blood volume take at this visit about 26mL or 1.8 tablespoons) to check for safety & kidney function, and blood for protein, RNA, TBNK, & exploratory analysis; blood for study drug concentration before you take your study drug
- A blood sample for fats (lipid panel) will be done at this visit and ***requires you to be fasting (water only) for at least 8 hrs. prior to site visit)***
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

Follow-up Period and Early Termination:

About 4 weeks later you will return to the study site for **Week 20, Day 141 Follow-up, End of Study** (visit should take about 1.0 hr.)

- A brief physical exam will be conducted including assessment of the skin and any problem areas
- Your blood pressure, temperature and pulse will be taken
- Blood samples will be taken (total blood volume take at this visit about 12mL or 0.8 tablespoon) to check for safety & kidney function
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel
- You should bring your hand-held device and any other study supplies requested by the site

If you decide to leave the study for any reason, it is important for your safety to return for an **Early Termination Visit (visit takes about 1.5 hrs)**

- A full physical exam including listening to your heart and lungs; looking in your eyes, throat, ears, checking reflexes and your abdomen will be performed.
- Your blood pressure, temperature and pulse will be taken
- An ECG (tracings of your heart) will be done
- Blood samples will be taken (total blood volume taken at this visit about 26mL or 1.8 tablespoons) to check for safety, kidney function, and blood for protein, RNA, TBNK, & exploratory analysis; and study drug concentration
- Urinalysis will be performed along with a urine pregnancy test for women who can have babies
- **You will bring back your study drug in original container to the site**
- The study doctor will assess your Hidradenitis suppurativa disease
- You will be asked questions about the severity and any change in your disease symptoms along with health survey and quality of life questions
- You will be asked about any medications, treatments or supplements you may be taking or have taken;
- The study doctor will discuss contraception with you
- You will be asked how you feel

About 4 weeks later you will then return to the study site for **Week 20, Day 141 Follow-up, End of Study, (visit should take about 1.0 hr)**. For details about End of Study visit, please refer to the paragraph above.

Description of Study Procedures and Assessments
Imaging Assessments

- **Chest X-ray:** X-ray is a procedure that produces images of the structures inside your body using radiation beams.
- **Chest CT Scan** is a test that uses a small amount of radiation (x-ray) to make pictures of the inside of your body. The test can show a cross section (a thin "slice") of your body, or can show the body tissues and structures in "3-D."
- **Chest MRI** or **magnetic resonance imaging** uses powerful magnets and radio waves to make pictures of body tissue and structure. During an MRI, you must lie on your back in the MRI scanner without moving. The inside of the MRI scanner might be a tight space.
- In some cases, X-ray, CT scan or MRI may show unexpected findings that are not the focus of this study. These are called "incidental findings." If the study doctor believes an incidental finding identified during the study is important for your health, the study doctor will explain it to you or to your personal doctor, with your permission (if your personal doctor is different from the study doctor). Your personal doctor can discuss next steps with you and decide if more tests or procedures are required.

The following biological samples will be taken in this study. You must provide these samples in order to take part in this study.

The samples may be stored in a facility located in a different country from your study site. Additional samples may be collected depending on the results of your laboratory tests or if a replacement sample is needed.

Blood Samples: Blood draw is the process of collecting blood from a vein through a needle. The needle is connected to a small tube in which the blood is stored until it is tested. If only a very small amount of blood is needed, it may be collected through a finger stick. In that case, your finger would be pricked by a small sharp point and the drops of blood collected.

- You will need to fast (not eat or drink anything) on Baseline visit, Weeks 8 and 16 for lipid panel testing. Blood sample(s) will be taken and used to conduct the tests and analyses described below.
    - **Safety Testing:** Hematology, chemistry, lipid panel and blood work as described above. A pregnancy blood sample will be taken for women who can have children.
    - **Pharmacokinetics (PK) and pharmacodynamics (PD):** You will have blood samples taken as indicated in the above table.
        - Study drug concentration samples called Pharmacokinetic (PK) Samples: will be taken pre-dose on the baseline visit, Weeks 1,2,4,6,8,12, and 16. On week 8 blood will be drawn one half hour after dosing, 1 hr., 2 hrs. and 4 hours post-doing. Also, if you leave the study early, a study drug concentration blood test will be done. A blood sample will be taken to measure the amount of study drug in your blood. This sample may be used to determine how the study

drug is changed and eliminated from your body after you take it. This sample may also be used to develop and/or evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers, as well as for other internal exploratory purposes.

- Pharmacodynamic (PD) Samples: A blood sample will be taken to determine how your body responds to the study drug and/or disease progression. The relationships between amount of study drug in your blood and how your body responds to the study drug may be evaluated. This sample may also be used to develop and/or evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers, as well as for other internal exploratory purposes.

Blood samples will be taken and used to conduct the tests and analyses described below.

- **Samples for HIV, Hepatitis B & C and tuberculosis tests:** You will be required to give blood samples for these tests as indicated above.
  - Hepatitis is inflammation of the liver, which can commonly be due to viral infection known as Hepatitis B or C infection.
  - HIV (human immunodeficiency virus) is a condition where the virus lowers your body's immune system's ability to fight infections caused by other germs such as viruses, fungi and bacteria.
  - Tuberculosis is a disease caused by a germ (bacteria) called Mycobacterium tuberculosis and usually affects the lungs, but it can also affect other parts of the body.
  - The results of all of these blood tests, just like all other laboratory test results, will be provided to the Sponsor. Positive HIV, Viral Hepatitis and TB test results may be reportable to local health authorities according to local laws.
- **Sample for pregnancy test** will be used to test for pregnancy. This applies only to women participants who can have children.
- **Sample to confirm postmenopausal status** in women may be taken.
- **Samples for banked biospecimens**. A 10.54-mL sample of your blood will be collected and sent to the Sponsor's biobank (the Sponsor calls these samples "Banked Biospecimens"). These samples will be used to study biological substances in your sample(s), including your genes. This will help us learn more about the study drug and Hidradenitis Suppurativa.
  - These samples may be kept by the Sponsor in a facility approved by the Sponsor as long as the samples are useful for scientific research, which may be for many years (no time limit).
  - The samples can be held at PPD until the end of the study and then shipped to the following address:
    - BioStorage Technologies Inc., Fortune Circle West, Suite E, Indianapolis, IN 46241, USA
- Additional blood samples may be collected at any time during the study if needed to evaluate your well-being.

- Your blood samples may also be tested for exploratory biomarker research related to the study drug.
- **Urine samples**
  - **Samples for safety testing:** these samples will test substances in your urine to help evaluate your overall well-being.
  - **Samples for pregnancy test** will be used to test for pregnancy. This applies only to women participants who can have children.
  - **A urine drug test will be done at screening.**
- **Samples for safety testing:** these samples will test substances in your blood to help evaluate your overall well-being.
- **Skin test (PPD):** PPD test for TB will be done at screening.
- **Clinical Assessments** of your disease will be done by the study doctor at the study visits. These will include lesion counts and measurements, and assessment of abscesses and tracks.
- **Questionnaires:** You will be given a hand-held device to take home and instructions on its use to answer questions about pain and your disease. At site visits, you will also be asked questions about your quality of life and disease. It should take about 15 minutes to complete these questionnaires.
- **You will be asked about any medication you are taking (including topical medications and treatments, over-the-counter and prescription medications and treatments, and vaccinations) at each study visit.**
- **You will be asked about how you're feeling at each visit.**

It is very important you bring back your study drug bottle or blister card at each site visit whether empty or with drug remaining.

Skin swabs for rash: this will be taken only if, at any time during the study, your study doctor thinks you may have a blister skin (herpetiform) rash. A blood sample will also be obtained.

The Sponsor may share the samples and/or data derived from the samples or through your participation in the study with third parties (such as other researchers and collaborators at other institutions and companies) consistent with the uses described above.

The study team may contact you after your participation in the study has ended to learn more about how you are doing.

Drug Access after Study Completion

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

7. Are there any special instructions to follow for this study?

It is important that you:

- Tell the study doctor 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.
- Do not take part in any other study without approval from the study doctor. Tell the study doctor immediately if you are taking part, or want to take part, in other studies while you are taking part in this study. Participating in more than one study at the same time could put your safety at risk.
- Take part in the study only at this location. Participating in this study at more than one study site at the same time could put your safety at risk and is not permitted.
- Follow the instructions you are given by the study doctor and study team. If you do not follow the instructions, your visit may have to be rescheduled and/or you may not be allowed to continue to participate in this study.
- Tell other doctors, nurses, and health care providers about your participation in this study by showing the information card provided to you by the study team.
- Tell the study doctor or the study staff about all prescription and non-prescription medications, supplements, or vaccines (for example, flu shot) before you take them.
- Notify the study team if you move and provide your new contact information
- Do not throw the study drug in the trash or flush it down the toilet. Do not give your study drug to any other person. Keep the study drug out of the reach of children and others who cannot read the label.

Lifestyle Instructions

- On three of the study visit days, you will have to fast (water only) for at least 8 hours prior to the visit.
- On study visit days, do not smoke or ingest caffeine (for example, tea, coffee, some soft drinks/colas/energy drinks and power bars) during the 30 minutes prior to blood pressure and pulse (heart) rate measurements.
- On study visit days, you should refrain from taking your drug at home. Dosing will be administered while at the study site.
- On study visit days, you can take prescribed permitted concomitant medication, as needed, prior to the study visit, if it can be administered with water only. Prescribed permitted concomitant medications that must be taken with food or after meals should not be taken until after the visit procedures have been completed.
- Contact the study doctor if there are any changes or additions to concomitant medications.
- You should not do strenuous exercise (for example, heavy lifting, weight training, calisthenics, and aerobics) for at least 2 days prior to each blood collection. Walking at a normal pace is allowed.
- You should not eat grapefruit or grapefruit juice or a citrus fruit like Seville oranges or pomelos for 7 days before the first dose and until the final drug concentration blood sample has been collected.

- You should stop taking all herbal supplements 28 days before the first dose of study medication and throughout your participation in this study.
- You can take vitamins, minerals and purified food substances in amounts not known to be associated with adverse effects so it is important you tell your study doctor what you are taking.
- You should not receive live vaccines while you are in the study and avoid close contact with others who are sick (contagious) or have recently received a live vaccine. Please consult your study doctor for more information.
- You may shower or bathe prior to attending study visits; however, moisturizing should be avoided.
- You are required to use an over the counter daily antiseptic wash which you will receive at your site.
- If you take Metformin, you must wait at least two hours after taking the metformin before taking the study drug.

8. What are the possible risks and discomforts of this study?

All research has some risk, which may include things that could make you feel unwell or uncomfortable, or that could harm you. You might experience these risks or discomforts while taking part in this study. It is important that you tell the study team if you are feeling any of these things during the study. The study team will monitor you for risks or discomforts during the study. However, the study team does not know all of the effects that the study drug, or your participation in this study, may have on you. These effects might be mild or serious. In some cases, these effects might be long-lasting or permanent, and might even be life-threatening.

The study team may determine that you need additional clinical procedures or medicines to help manage side effects. The study doctor also may decide to remove you from the study.

If you take part in this study, the most likely risks or discomforts to happen to you are discussed below.

It is important that you report to the study team all symptoms and side effects as soon as they occur. Phone numbers for the study team are listed on page one of this consent document.

Study Drug PF-06700841 Risks

As of August 21, 2019, there are five completed clinical studies with the investigational drug PF-06700841 in healthy volunteers (in single doses up to 200 mg and multiple doses up to 175 mg daily for 10 days), in healthy Japanese participants (multiple doses of 100 mg daily for 10 days), in participants with psoriasis (doses up to 100 mg daily for 28 days, or 60 mg daily for 4 weeks, followed by up to 30 mg daily or 100 mg weekly for 8 weeks), and in participants with alopecia areata (at an induction dose of 60 mg for 4 weeks, followed by a maintenance dose of 30 mg daily for 20 weeks). Results from these studies indicate that PF-06700841 is generally well-tolerated.

There were no significant changes in vital signs or electrocardiogram data that have led to study drug discontinuation. In the completed clinical studies with PF-06700841, the adverse events that were reported in more than 5% (1 in 20) of participants with psoriasis or alopecia areata administered multiple doses of PF-06700841 were upper respiratory tract infection, nasopharyngitis, bronchitis, sinusitis, folliculitis, headache, nausea, diarrhea, acne, and decreased white blood cells although the association with study drug is unclear.

Serious or Unusual Infections

Given the expected effects of PF-06700841 on the body's ability to fight infections, infection is a potential risk in humans. The most common infections observed include bronchitis, nasopharyngitis, sinusitis, upper respiratory tract infections, and urinary tract infections. Except for 1 participant who experienced a serious infection of pneumonia after taking one dose of PF-06700841 and a case of a viral infection [cytomegalovirus (CMV)] in a participant on blinded treatment, most infections were mild to moderate in severity during treatment periods in clinical trials. You should not start taking PF 06700841 if you have any kind of infection. After starting PF-06700841, call your study doctor right away if you have any symptoms of an infection. Symptoms of an infection could include fever, weight loss or excessive tiredness or other symptoms specific to the site of infection, such as a persistent cough. PF-06700841 can make you more likely to get infections or make worse any infection that you may already have

Reactivation of Viruses

Certain viruses can be stored in the body and they may reactivate (wake up) and cause negative effects, such as chicken pox virus (herpes zoster) which causes shingles (a painful or burning skin condition), and herpes simplex virus which causes cold sores or fever blisters in the mouth or genital ulcers. There was one case of shingles (herpes zoster infection) in an individual who was administered PF-06700841 at a daily dose of 100 mg, which is higher than the current clinical trials using multiple doses. No additional cases of herpes zoster have been reported with PF-06700841 in other completed and ongoing studies to date.

We do not know if PF-06700841 or other similar medications could lead to the reactivation of hepatitis viruses. You will not be allowed to participate in the study if your blood tests show that you have had hepatitis types B or C viruses or if you have had history of repeated episodes of Herpes Zoster. During the study, you should inform your study doctor (either by phone or when you next visit the clinic) if you think you may have shingles, ulcers in the genital area, or cold sores.

Cancer

PF-06700841 may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphoma (blood cancer) and other cancers, including skin cancers, have occurred in patients taking medications that work in a similar way to PF-06700841.

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 and those who have had successfully treated local cancer of the cervix (the lower part of the uterus). Talk to your study doctor if you have had any type of cancer.

Changes in certain laboratory tests

PF-06700841 can affect hematological parameters (blood cells) in humans, including red blood cells, white blood cells, platelets (small particles in the blood that help with clotting), and other blood cell types. For this reason, your study doctor will do blood tests before you start taking PF-06700841 and while you take PF-06700841. Some changes in blood tests that have occurred in earlier studies with PF-06700841 are described below. You will have these blood tests at most visits and you will be discontinued from the study if your blood counts drop to a level which would cause concern for your continued participation in the study.

- Changes in lymphocyte counts. Lymphocytes are a type of white blood cell that help the body fight off infections. If your lymphocytes are low, you might be more likely to have an infection.
- Decreases in neutrophil counts. Neutrophils are another type of white blood cell that help the body fight off infections. If your neutrophils are low, you might be more likely to have an infection.
- Changes in platelet counts. Platelets are a type of 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 or increased clotting related to increased platelets have not been seen in previous studies with PF-06700841, there is still a potential risk that these events could happen. Increases in serum creatinine. Serum creatinine is a chemical that is measured in the blood to see how well your kidneys work. Increased creatinine levels in the blood may indicate that kidney function is impaired. In completed studies with PF-06700841, increases in serum creatinine were seen, but not associated with worsening kidney function. For this reason, your study doctor will be monitoring your kidney function throughout the study.
- Increases in serum creatine phosphokinase. Creatine phosphokinase is a protein that leaks out of muscle tissue and if the levels are high this could signify muscle injury. Very high levels of creatine phosphokinase may result in a condition called rhabdomyolysis, which may lead to muscle pain, tenderness, weakness and/or kidney injury. In the alopecia areata study, 2 cases of rhabdomyolysis were reported without kidney injury.
- Increases in hepatic transaminases. Hepatic transaminase is a chemical that is measured in the blood to see how well your liver works. In completed studies with PF-06700841, mild increases in hepatic transaminases were seen. For this reason, your doctor will be monitoring your liver function throughout the study and participants with history of impaired liver will not be eligible for the study.
- Changes in other laboratory tests, such as your blood cholesterol or hemoglobin (red blood cells) levels may also be seen. Those tests and others will be checked on a regular basis throughout the study to make sure they are not changing aberrantly.

Changes in electrocardiograms (ECG)
Studies with PF-06700841 have been conducted in animals and humans to identify potential risks related to electrocardiogram (ECG) changes that may occur in people who are administered PF- 06700841. In animals, a modest change in the ECG, called QT prolongation, was noted following treatment with PF-06700841 at exposures (blood levels) 6 to 10 times higher relative to the highest dose (60 mg) being developed for human use. A study to assess the potential for PF -06700841 to affect the ECG in healthy humans showed modest changes in QT prolongation with a dose more than 3-fold higher than the highest doses being studied in patients. To date there have been no reports of adverse ECG changes in humans in clinical studies with PF-06700841.

As a result of these ECG studies, a number of precautionary measures will be included in this study, including the following:

- Certain products (medicines or foods) known to affect the ECG ("QT prolongation") will disqualify you from entry into the study or lead to early termination from the study if you start these products during the study. If you have questions about these products, or any new medications, talk with your study doctor.
- Your doctor will be monitoring your heart rhythm throughout the study with ECGs (electrocardiograms).

Deep vein thrombosis and pulmonary embolism
Pulmonary emboli have occurred in patients taking medications that work in similar ways to PF- 06700841. Thus PF- 06700841 may increase the risk of developing a blood clot, including in your legs (deep vein thrombosis) and lungs (pulmonary embolism). A serious adverse event of DVT occurred in a female healthy participant taking both PF-06826647 and oral contraceptive in C2501005, a Phase 1 Drug-Drug Interaction Study. If you have had a history of recent blood clots in your legs or lungs or a history of repeated blood clots in your legs or lungs, or have other risk factors for clotting, you may not be eligible for this study. Please let your doctor know if you have a history of blood clots.

Studies with PF-06700841 have also been conducted in animals (6-month studies in rats and 9-month studies in monkeys) to identify potential risks that may occur in people who are given PF-06700841 for a longer period of time. In the animal studies, no PF-06700841-related adverse findings were noted.

There may be rare and unknown side effects with taking PF-06700841. Some of these side effects 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. If you do not understand the findings in the human clinical trial or the animal studies described above, please ask the study doctor or study staff to explain them to you.

Study Drug PF-06650833 Risks

PF-06650833 is a new class of drug that works by decreasing the activity of a part of the immune system known as the "innate immune system". The immune system is made up of special types of cells and proteins whose job is to prevent, and fight, infections caused by "germs" (such as bacteria and viruses) that make people sick. The innate immune system is the body's first line of defense against such germs. When the body detects germs, the immune system becomes active. Sometimes, the immune system becomes too active or by mistake attacks your own body, which leads to disease. PF-06650833 is designed to control such excess activity of the innate immune system.

PF-06650833 is in the early phase of clinical development. This means that only a relatively few people have received the drug to this point. Our understanding of the safety of PF-06650833 is therefore not complete. There may be undesirable (negative) side effects, also known as adverse events (AEs), including serious or severe reactions that have not yet been discovered.

The safety profile of PF-06650833 reflects data from early clinical studies in people, and studies conducted in animals. Since PF-06650833 is a new class of drug, there are no similar drugs already approved that could provide more information about the potential safety of PF-06650833.

Human Studies

As of 01 August 2019, PF-06650833 has been administered to 354 people among 7 clinical studies conducted in healthy people up to 14 days in duration and 1 study in participants with rheumatoid arthritis (RA). PF-06650833 has been generally well-tolerated in the doses given to people in clinical trials to date with a safety profile that continues to support its study as a possible treatment of disease. Doses up to 4000 mg per day for up to 14 days have been given to healthy people and doses up to 400 mg per day for up to 12 weeks have been given to participants with RA.

Undesirable (adverse) effects in humans

As of 01 August 2019, no safety risks or potentially important risks have been identified in people given PF-06650833. There has been 1 serious adverse effect in a participant with RA that was considered possibly related to PF-06650833.

In general, undesirable (adverse) effects have been mild to moderate in severity and have not required treatment. The chance of getting an undesirable effect, or how severe it is, has not seemed to be related to the dose of PF-06650833. The most common undesirable effects in the studies in healthy people up to 14 days, have been headache and a variety of stomach and intestinal-related effects (most commonly, abdominal pain, nausea, and vomiting). The most common undesirable effects (occurring in greater than or equal to 5% of people) reported in study of PF-06650833 in participants with RA were abdominal pain, nausea, respiratory tract infections (such as sore throats, colds, and bronchitis), rheumatoid arthritis, and headache.

Most of these undesirable effects occurred at the same rate in people taking PF-06650833 and people given a "dummy" drug (a "placebo") like a sugar pill that had no activity. Only infections may have occurred more frequently in people taking PF-06650833 than a "dummy" drug, but the numbers of people with infections were too small to be certain.

Effects on Liver Protein on liver protein levels

Increases in blood levels of certain liver proteins (enzymes) above the level of normal have been seen in a small number of both healthy people and participants with RA receiving PF-06650833. Very large increases in the blood levels of these liver proteins may indicate injury or damage to the liver. In most cases, the increases in these liver enzymes in people receiving PF-06650833 were low and were not associated with any symptoms (signs of liver disease). The levels of these proteins returned back to normal levels either during or shortly after the completion of dosing. Importantly, no participant showed signs or other laboratory tests suggestive of clinically significant liver injury.

One (1) participant with moderately to severely active RA who received the lowest dose (20 mg per day) of PF-06650833 in the 12-week RA study developed very large increases in blood levels of liver proteins about 5 weeks after the start of dosing with PF-06650833. This was reported as a serious adverse event (undesirable, or negative, effect) with the term of "liver injury" and was considered as possibly related to treatment with PF-06650833. However, the participant did not have other blood tests that would put the participant at high risk for liver injury caused by drug treatment. In addition, other specific tests to confirm liver injury were not performed.

The patient also had other medical conditions and was taking other drug that may also have contributed to the large increases in liver enzymes.

Review of tests from all other participants in the RA study showed that only a few people had any increases above normal in blood levels of liver enzymes. These increases were generally low and not clinically significant. The number of people with increases in blood levels of liver proteins did not increase with increase in dose of PF-06650833.

Therefore, considering all information from people treated with PF-06650833 as of 01 August 2019, there is not enough evidence to consider increases in liver enzymes a safety risk for people taking PF-06650833 at clinical doses. In addition, current data suggests that the increases in liver enzymes would be get better if found early and treatment with PF-06650833 is stopped. Blood tests will be performed to look for changes in liver proteins in clinical trials with PF-06650833.

Effects on kidney function and urine

PF-06650833 may cause an unusual type of crystals (particles like grains of salt) to be found in the urine when looked at under a microscope. These unusual crystals were seen occasionally in the studies in healthy people, especially in people receiving the highest doses of PF-06650833 (750 mg twice-a-day and 1000 mg 4 times-a-day).

Only 2 people in the 12-week RA study were found to have unusual crystals in the urine. People who had crystals seen in the urine did not have any symptoms and did not report any unfavorable side effects (participants have generally not been aware that they had crystals in the urine). Importantly, no harmful effects on kidney function have been seen in people who had unusual urine crystals. Based on chemical testing, these unusual crystals are likely composed mostly of breakdown products of PF-06650833.

Unusual crystals have also been seen in safety studies in rats given PF-06650833. In most cases, no harmful effects were seen in the kidneys. In rats receiving very high doses PF-06650833 for 3 months, harmful effects to the kidney, including kidney failure, were seen that may have been related to deposits of crystals in the kidneys. However, harmful effects in the kidneys were not seen in longer (26-week) studies in rats. No unusual urine crystals were seen in rats followed 8 weeks after dosing in the 3-month study or for 1 month after dosing in the 26-week study. No harmful effects in the kidneys have been seen in dogs given PF-06650833 for up to 39 weeks.

Clinical experience with marketed drugs that produce crystals in the urine suggests that the risk of kidney injury may be decreased by avoiding dehydration (by drinking adequate amounts of water). Data would also suggest that, if caught early, harmful effects on the kidney would get better when the study drug is stopped.

The totality of human and animal data suggests that people taking PF-06650833 are not likely to develop unusual urine crystals at planned clinical doses.

Furthermore, unusual urine crystals, if they are present, are likely not to cause any symptoms (that is, will not be noticeable) and are very unlikely to cause harmful effects on the kidneys. Doses of PF-06650833 in humans will be below the level at which kidney injury was seen in animals. In addition, people taking PF-06650833 will be encouraged to drink plenty of fluids. They will also be monitored closely with physical examinations, and blood and urine tests for the development of urine crystals and / or kidney injury.

<u>Other serious undesirable effect or discontinuations due to non-serious undesirable effect observed in humans</u>

As of 01-August-2019, there have been no deaths in any clinical study and no serious undesirable (adverse) effects in early studies in healthy people. Two (2) healthy people were discontinued from a 14-day study due to non-serious side effects. One person who received 750 mg PF-06650833 twice-a-day developed decreased appetite that was accompanied by nausea, vomiting, and abdominal pain. No one else receiving the same or higher dose of PF-06650833 had similar problems. One healthy person in the 14-day study had 2 blood tests in a row with low numbers of a type of white blood cell known as a neutrophil. This person had lower numbers of neutrophils in the blood before starting to receive PF-06650833 and may have normally low neutrophil counts.

Six (6) participants in the 12-week RA study developed serious undesirable effects while taking one of several different doses of PF-06650833. Three (3) of these people were discontinued from the study due to these undesirable side effects. Only 1 of these serious undesirable effects was considered possibly related to PF-06650833. This was the case of highly elevated blood levels liver proteins discussed above. One of the cases was a foot infection. One person had multiple serious events due to trauma (injury).

Studies in animals

Studies up to 26 weeks in rats and 39 weeks in dogs have been conducted in animals to identify potential undesirable effects of PF-06650833. These involved much higher doses and exposures (blood levels) of PF-06650833 than given or seen in people. In these studies, harmful effects (changes) in the kidneys (as described previously), the heart and blood vessels surrounding the heart, skeletal muscle, the liver, and in the gastrointestinal (GI) tract have been seen at high blood levels of PF-06650833. Doses of PF-06650833 in planned clinical studies will be selected that are projected to produce blood levels of PF-06650833 below the maximum blood levels at which no harmful (adverse) effects were seen in animals.

Animal studies suggest that PF-06650833 may increase heart rate (pulse) and / or decrease blood pressure at high exposures. Data in dogs also suggest that PF-06650833 may cause a small increase in a measurement in an electrocardiogram (ECG) known as the QTc interval. An ECG measures the electrical activity of the heart that controls its beating, and the QTc interval is a measure of the heart's rate of recovery from a contraction (beat).

To date, no clinically significant adverse effects on blood pressure, pulse, or ECG values (including QTc), or changes in physical examination have been found in people who have been exposed to PF-06650833 in early clinical trials. People participating in clinical trials of PF-06650833 will have their blood pressure, pulse, and ECGs monitored for effects on the heart.

OTHER POTENTIAL UNDESIRABLE (SIDE) EFFECTS

Serious or unusual infections

As noted in the Introduction, above, PF-06650833 is designed to inhibit (reduce the activity of) specific parts of the immune system. Although harmful effects of PF-06650833 on the immune system or increased rates of infection were not seen in animals, any drug that decreases the activity of the immune system may decrease the body's ability to fight infection. PF-06650833 may therefore increase the risk of infection, allow an infection to become more serious, or allow someone to develop infections that don't usually occur in people with a normal immune system. People with active or hidden (latent) infections, such as tuberculosis, should not start taking PF-06650833. People taking PF-6650833 will be monitored for infection with physical examinations (including temperature), laboratory testing, and questions about their general health. Anyone taking PF-06650833 should report any signs or symptoms of infection to their study doctor as soon as possible.

Reactivation of viruses

Certain viruses can be stored in the body and they may reactivate (wake up) and cause negative effects. For example, reactivation of the chicken pox virus (herpes zoster) causes shingles (a skin condition with blisters, accompanied by burning or pain which my last after the rash clears), and reactivation of the herpes simplex virus can cause cold sores or fever blisters in the mouth or genital ulcers.

It is not known if taking PF-06650833 could lead to the reactivation of herpes viruses. People who have had serious episodes of shingles or herpes simplex breakouts (for example, had rashes extending over large areas of the body, had required hospitalization, or had affected organs other than the skin) should not take PF-06650833.

People with other types of hidden virus infections such as hepatitis virus or human immunodeficiency virus (HIV, the virus that causes AIDS) should also not start taking PF-06650833. People will be tested for hepatitis and AIDS viruses and will not be allowed to participate in clinical trials with PF-06650833 if the blood tests show that they have hepatitis or AIDS.

People who may be taking PF-06650833 are to call their study doctor right as soon as possible if they think they may have shingles, ulcers in the genital area, cold sores, or signs of liver failure such as yellowing of the white part of the eyes, dark urine, or clay-colored stool.

Since the potential effect of PF-06650833 the ability to fight virus infection is not known, live vaccines should not be taken shortly before or while taking PF-06650833.

Changes in certain laboratory test results

Studies in rats indicate that PF-06650833 may decrease number of white blood cells, including a type of white blood cell known as a lymphocyte, in the blood and organs such as the spleen. These findings were of low severity or small and therefore not considered harmful. No changes on average in blood the numbers of white cells, neutrophils, lymphocytes (or red blood cells) have been seen in clinical studies as of 01-August 2019. Low numbers of white blood cells, including neutrophils and lymphocytes, may increase the risk of infection.

Study Drug (PF-06826647) Risks

PF-06826647, also known as the study drug, has been studied in animals and humans, as summarized below, but not all product safety information is known at this time. There may be rare and unknown side effects, also known as adverse events (AEs), including serious or severe reactions that have not yet been discovered.

Human Studies

Human studies with PF-06826647 consist of one completed Phase 1 study (C2501001).

A total of 69 healthy participants and 40 participants with plaques psoriasis received study treatments. All reported adverse events were mild in severity except for one adverse event that was moderate in a psoriasis participant receiving placebo. There were no serious or severe adverse events observed.

Animal Studies

Studies have been conducted in animals to try to identify risks that may occur in people given PF-06826647. In some animals given high doses of PF-06826647, increases in blood pressure and heart rate occurred. Some animals had discolored feces and gastric reflux. These effects occurred generally at high dose levels of PF-06826647. Based on animal studies, PF-06826647 may increase levels of certain proteins in the blood, which may indicate inflammation or injury to the liver. Rats and monkeys given PF-06826647 had increases in liver enzymes. However, these increases were not associated with signs of liver injury in animals. There is also the potential for changes in blood lipid levels (cholesterol and triglycerides) with PF-06826647. Lipid changes seen in animals were small and not associated with evidence of liver or other tissue injury. Decreases in certain immune cells (white blood cells) also occurred in some animals receiving PF-06826647. These immune cells normally help protect against infection.

Potential Side Effects

Reactivation of viruses

Certain viruses can be stored in the body and they may reactivate (wake up) and cause negative effects.

In studies with PF-06826647 or other similar medications, reactivation of the chicken pox virus (herpes zoster) has caused shingles (a skin condition with blisters, accompanied by burning or pain which my last after the rash clears), and reactivation of the herpes simplex virus has caused cold sores or fever blisters in the mouth or genital ulcers.

We don't know if PF-06826647 could lead to the reactivation of hepatitis viruses. You will not be allowed to participate in the study if your blood tests show that you have had hepatitis types B or C viruses (unless demonstrated to be completely cured from Hepatitis C). During the study, call your study doctor right away if you think you may have shingles, ulcers in the genital area, or cold sores. For the same reason described above, live vaccines should not be taken prior to or after taking PF-06826647 according to protocol.

Serious or Unusual infections

PF-06826647 is a study drug that affects your immune system. It may lower the ability of your body to fight infections, leading 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 medications similar to PF-06826647. You should not start PF-06826647 if you have any kind of infection. After starting PF-06826647, call your study doctor right away if you have any symptoms of an infection. Symptoms of an infection could include fever, weight loss or excessive tiredness or other symptoms specific to the site of infection, such as a persistent cough. PF-06826647 could make you more likely to get an infection or may worsen any infection that you may already have.

Cancer

PF-06826647 may increase the risk of certain cancers by changing the way your immune system defends against cancer. Lymphoma and other cancers, including skin cancers, have been reported in participants taking medications that work in a similar way to PF-06826647. 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 and those who have had successfully treated local cancer of the cervix (the lower part of the uterus). Talk to your study doctor if you have had any type of cancer.

Changes in certain laboratory test results

Your study doctor will perform blood tests before you start taking PF-06826647 and while you take PF-06826647. Some changes in blood tests that have occurred in animal or human studies with PF-06826647 are described below. You will have these blood tests at every visit and you will be discontinued from the study if your blood counts drop or rise to a level which could affect your continued participation in the study.

- Decreases in lymphocyte counts. Lymphocytes are a type of white blood cells that help the body fight off infections. If your lymphocytes are low, you might be more likely to have an infection.
- Decreases in neutrophil counts. Neutrophils are a type of white blood cells that help the body fight off infections. If your neutrophils are low, you might be more likely to have an infection.
- Increases in platelet counts. Platelets are a type of blood cells that help blood to clot. If your platelets are too high, you might be more likely to have a blood clot. Although clotting related to high platelets has not been seen in previous studies with PF-06826647, there is still a potential risk that this could happen.
- Changes in other laboratory tests, such as a rise in muscle enzymes (creatine kinase), kidney function parameters (serum creatinine), blood cholesterol or a drop in hemoglobin (red blood cells) levels, may also be seen. These tests and others will be checked on a regular basis throughout the study.

Risks from Study Procedures

Risks and possible discomforts you might have from the study procedures include:

- **Blood draws:** A blood draw may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.
- **Chest X-Ray**: A chest x-ray exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health.
- **CT scan:** A CT scan exposes you to a small dose of radiation. Although all radiation you receive builds up over your lifetime, this amount of radiation should not create a significant risk to your health.
- **MRI:** There are risks from an MRI if you are pregnant or have one of the following, for example: an artificial heart valve, pacemaker, metal plate, pin, or other metallic objects in your body (including from a gunshot or shrapnel). You may also become anxious from the loud noise or lying in a tight space without moving. The MRI scan does not cause any pain and does not expose you to x-ray radiation.
- **ECG:** The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the sticky patches.
- **Fasting:** Fasting could cause dizziness, headache, stomach discomfort, or fainting.
- **Testing of DNA and/or RNA:** Genes are pieces of DNA that, which 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 (called "whole genome sequencing"). Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes. The genetic analysis is for research purposes only, and is not a medical test. This means that the medical importance of the results may not be known, or that they may not be related to any medical condition. The results of tests on your sample will not be given to you, the study doctor, any insurance company, your employer, your family, or 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. The Sponsor and study doctor will put measures in place to minimize the possibility for the results from this research being linked to you, but there is always the remote possibility that information from your participation in the research may be disclosed.
- **Questionnaires:** A questionnaire may contain questions that are sensitive in nature. If you have concerns after completing the questionnaire, you should contact your study doctor.

Other Risks
There may be other risks that currently are unknown because the study drug is investigational. If you or your partner are or might become pregnant, these unknown risks could affect you or your embryo or fetus. All drugs have a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives or blisters.

Pregnancy-Related Risks; Use of Birth Control
At this time, the effects of **PF-06700841** on male and female fertility, and pregnancy in humans, and effects on fetus or a nursing child are not known. In animal developmental studies, some pregnant animals who were administered PF-06700841 produced fetuses with fetal skeletal malformations (rats) and lower fetal viability (rats and rabbits). A cleft lip was reported in the unborn fetus of a human participant who became pregnant while participating in the completed PF-06700841 psoriasis study. The participant was also taking other medications at this time, including an herbal supplement with a warning against use during pregnancy. Because of the investigational nature of PF-06700841, it should not be administered to pregnant women, breastfeeding women, or fertile women of childbearing potential who are unwilling or unable to use contraception as defined in the study protocol. Strict use of birth control by women and men must be followed, as explained by the study doctor and study staff.

Studies of **PF-06650833** in pregnant rats suggest that high exposures of PF-06650833 may cause abnormal fetal development. These effects were observed at exposures that are higher than the maximal exposure in humans. The observations do not change the safety profile of PF-06650833 in non-pregnant, mature adults. Pregnant women should not take PF-06650833. Women capable of getting pregnant who PF-06650833 will be required to use at least 1 form of highly effective means of contraception. Preferably this method should not be dependent on a person remembering to use it (like birth control pills, condoms, etc.). Women taking PF-06650833 will be monitored for pregnancy prior to starting to take the drug and during the time of exposure.

When studied in rats, PF-06650833 did not affect fertility or early embryonic development up to the highest dose tested.

It is not known if PF-06650833 can get into breast milk. Therefore, PF-06650833 should not be given to women who are breastfeeding (nursing) an infant.

In animals, **PF-06826647** was associated with toxicity to the fetus. Because of this and the investigational nature of PF-06826647 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.

It is not known if PF-06826647 can affect male or female fertility. It is not known whether PF-06826647 is secreted into human milk Because of this and the investigational nature of PF-06826647, it should not be administered to breastfeeding women.

If you do not understand any of the findings described above, please ask the study doctor to explain them to you.

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

If you are **male** you must agree to the following requirements during the treatment period and for at least 28 days after the last dose of study drug, ***plus*** an additional 90 days:

- Refrain from donating sperm.

PLUS either:

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

OR

- Must agree to use a male condom consistently and correctly.
- Use of an additional highly effective contraceptive method for your female partner if she is able to have children. Your study doctor will discuss this with you in further detail.

For a **female** eligible to participate in the study, you must either be:

- Not able to have babies

OR

- Is able to have babies and using a contraceptive method that is highly effective during the study period and for at least 28 days after the last dose of study drug. You may need to use an additional barrier method depends on the contraceptive method. Your study doctor will discuss this with you in further detail.

Birth control methods are not perfect, even when used properly.

If you or your partner become pregnant during the study, or you want to stop your required birth control during the study, you should tell the study doctor 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 female partner become pregnant while you are taking study drug during the study you must stop taking the study drug, please tell the study doctor **immediately**.

If you or your female partner become pregnant anytime during the 28 days after the last dose of study drug, please tell the study doctor **immediately**.

Please also tell the doctor who will be taking care of you or your female partner during the pregnancy that you took part in this study. The study doctor will ask if you, your female partner, your pregnancy doctor or your female partner's pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. Your female partner may be asked to sign a separate informed consent in order to collect this information. If you or your female partner agree, this information will be provided to the Sponsor for safety follow-up.

9. What are possible benefits of this study?

It is possible that your condition or health may improve, worsen, or stay the same because you are taking part in this study. There is no guarantee that you will benefit in any way. However, your participation in this study may benefit future patients.

10. What other choices do I have if I do not join this study?

Instead of taking part in this study, you may choose to receive treatment with other Hidradenitis suppurativa drugs or treatments that have been approved for use in your country. Your study doctor can discuss with you the available alternative treatments, and the major risks and benefits associated with their use.

Ask the study doctor for your estimated recovery time from the study treatment or procedures done during your participation in this study.

11. What happens if I am injured during this study?

If you experience a research injury, the study doctor will provide or arrange for medical treatment. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing and dating this form.

If you are treated for a research injury that is paid for by Pfizer, Pfizer or its representative will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services, in accordance with CMS reporting requirements. Pfizer will not use this information for any other purpose.

This study involves HIV-related information.

The release of any HIV-related information to Pfizer does not permit Pfizer to re-disclose such information without your consent, unless permitted to do so under applicable state law. If you receive Medicare, by signing and dating this consent, you specifically authorize Pfizer and its representatives to disclose your HIV-related health information to CMS for the purpose of complying with reporting requirements.

12. What if I join this study and then change my mind?

If you agree to participate and then change your mind for any reason, you are free to stop participating at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study doctor if you are thinking about stopping or decide to stop so that you can end participation in the study in the safest way.

While you are participating, the study team will tell you in a timely manner if new information is learned during the course of the study that could change your mind about continuing in this study. If you decide to withdraw from the study, you may be asked to continue to participate in the study procedures even though you would no longer take the study drug.

If you agree to continue with the follow-up part of the study, information about your health will continue to be collected as described in Section 6.

If you decide to stop participating in this study, you must notify the study doctor. The study team will explain how to return the study drug and what other procedures or discussions would occur.

Sometimes the study doctor or the Sponsor may decide to take you out of the study (even if you do not agree) if:

- You are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to participate; or
- The study is stopped by the Sponsor, the institutional review board (IRB) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

The study team will give you a Privacy Supplement, which is considered part of this consent document. It describes what happens to your personal information (including your biological samples) and how it may be used if you withdraw from the study.

13. What will I have to pay for if I take part in this study?

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

Any other procedures performed for your regular medical care that are required for the study but are not covered by the Sponsor will be billed to your insurance, or to you if you do not have insurance. You will be responsible for any insurance copayments and deductibles that normally apply. Some insurance plans will not pay for these services for people taking part in research studies. Please check with your insurance company to find out what your insurance plan will pay for. No additional funds have been set aside by the Sponsor or the study site to cover regular care services that your insurance plan does not cover, so you may be financially responsible for those costs. Talk to the study team if you have any questions about costs that you may have as a result of taking part in this study.

14. Will I be paid for taking part in this study?

You will receive payment for taking part in this study. If you leave the study early for any reason, you will be paid $25 for each study visit you have already completed. You will be paid monthly.

The Sponsor may use information resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. The Sponsor will own all products or processes that are developed using information from the study.

15. What will happen to my personal information?

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

The study team will give you a Privacy Supplement, which is considered part of this consent document. The Privacy Supplement tells you about:

- What personal information may be collected from you during the study;
- How your personal information will be used and by whom (including by the study site, the Sponsor, and others outside the study site);
- How your biological samples and images will be handled (if collected);
- How your personal information might be used for other research;
- How your personal information will be protected during transfer;
- Your data protection rights, and whom you may contact about these rights or any related concerns or complaints; and
- What happens to your personal information if you decide to stop taking part in the study.

16. Where can I find additional information about this study or the study results?

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.

The study results, when available, may also be found on www.pfizer.com and https://www.clinicaltrialsregister.eu/.

These Web sites are in English only. If you need assistance understanding these Web sites, please ask a member of the study team.

If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individuals, including you. The Sponsor does not plan to return information from any exploratory research to you, the study doctor, or your doctor (if different from the study doctor).

17. 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, please contact the 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 subjects.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: **adviser@advarra.com**

Please reference the following number when contacting the Study Subject Adviser: Pro00039106.

18. Signatures

Agreement to Participate and to Process Data	Participant Initials
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have had the opportunity to ask questions. I have had enough time to review this consent document. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate.	
2. I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.	
3. I understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent to the processing of my personal information at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my biological samples may not be able to be destroyed because they may no longer be traceable to me, may have already been used, or may have been given to a third party.	
4. I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the course of the study, and if necessary, contacting my doctor or any other health care providers treating me for access to such information.	
5. I understand that the Sponsor and/or others working with or on behalf of the Sponsor, institutional review boards (IRBs), and regulatory agencies may need access to personal information about me generated at the study site or collected by the study team for the study and any other research. I agree that they may have access to my personal information.	
6. 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.	
7. I agree to take part in the study described in this document.	

Printed name of participant

Signature of participant

Date of signature§

§Participant must personally date their signature.

Person Obtaining Consent:

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion †

Date of signature

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

PRIVACY SUPPLEMENT

This Privacy Supplement describes how we will collect, use, and share your personal information. It also describes your privacy rights.

You are not required to authorize the use and disclosure of your personal information as described below. If you do not agree, you cannot participate in this study, but there will be no penalty or change to your regular medical care or payment for that care.

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

Your study team and others assisting with your study-related care will collect or provide information about you, some of which is sensitive. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, date of birth, and health insurance number/national ID number.
- **Sensitive 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 genetics, sexuality, HIV/AIDS, tuberculosis, substance use disorders, mental health disorders, diagnoses and treatment, race, ethnicity, religious beliefs.
- **Data from testing and analysis of biological samples** (such as blood or urine) **and images** (such as X-rays, CT-Scans, and medical photographs). This may also include genetic information.

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

Any personal information collected about you during this study will be stored by the study team at your study site. The study team must keep your personal information private. A U.S. privacy law called HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects the privacy of your personal health information. The study site must get your permission to use and share with others any personal health information that could identify you.

Your personal information will be accessed by:

- Your study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People, or organizations providing services for, or collaborating with, the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities (including the U.S. Food and Drug Administration and authorities in other countries); and
- Advarra Institutional Review Board (IRB) overseeing this study.

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;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- answer your data protection requests (if any).

The study site will retain your personal information for the period necessary to fulfill the purposes outlined in the consent document(s), which could be up to 15 years.

If you provide someone else's personal information (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us.

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

C. What happens to my personal information that is sent outside the study site?

The study site is required by HIPAA to protect your personal information. After your information is shared with others, such as the Sponsor, it may no longer be protected by HIPAA.

Before the study team transfers your personal information outside the study site, the study site will replace your name with a unique code and remove information that directly identifies you. We call this "**Coded Information**." The study site will keep the link between the code and your personal information confidential, and the Sponsor will not have access to that link. The Sponsor's employees and representatives are required to protect your Coded Information and will not attempt to re-identify you.

Your Coded Information will be used by the following:

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

The above parties may use your personal 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 Severe Hidradenitis Suppurtiva; and
  - Assessing the safety and efficacy 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 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); and
  - Sharing study data with other researchers not affiliated with the Sponsor or study team (including 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 or 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.

The Sponsor will retain your Coded Information for the period necessary to fulfill the purposes outlined in the consent document(s), which could be up to 15 years.

D. How are my biological samples and images handled?

If biological samples or images of you are taken during the study, those samples and images will be handled in the same way as your Coded Information. All samples will be treated as required by law. Sometimes your study site may be unable to remove information that can identify you from your images before sending images to the Sponsor and its representatives.

E. Can my personal information be used for other research?

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

This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources**: Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your Coded Information, which may include:
    - Limiting access to Coded Information to specific individuals who will be obligated to keep this information confidential and will be prohibited from attempting to re-identify your Coded Information.
    - Using security measures to avoid data alteration, loss and unauthorized access.
    - Anonymizing the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
    - Assessing data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.

- When required by applicable law, ensuring that the scientific research has the approval of IECs, IRBs, or other similar review groups.

F. How will my personal information be protected when transferred from the study site to the Sponsor?

Your personal information will be treated in compliance with applicable data protection laws, including requiring people and/or organizations providing services to or collaborating with the Sponsor to use appropriate measures to protect the confidentiality and security of your personal information. Some of the people using your personal information, including your Coded Information, may be based in countries other than your country. Data privacy laws may be different in these countries. If your personal information is transferred by the Sponsor to other countries, the Sponsor, and people working with the Sponsor, will take steps to maintain the confidentiality of your personal information.

G. What are my data protection rights? Whom may I contact about these rights or any concerns or complaints?

You have the right to access your personal information that is held about you by the study team. *To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.*

If you wish to exercise this right, or have concerns about how your personal information is being handled, it is best to contact the [Institution] and not the Sponsor. Generally, the Sponsor will not know who you are (by name) because the Sponsor usually holds only your Coded Information, which does not include your name or other information that can easily identify you. To contact the [Institution] or the study team representative, please see the **contact information on page one** of the consent document.

H. What happens if I do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time by telling the study team. Your authorization for the study site to disclose your personal information does not expire unless you withdraw your authorization.

In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign and date this authorization document.

You may withdraw your authorization at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you and check whether you wish to continue in the study. If the study site is unable to reach you, the Sponsor may use publicly available records about your health to monitor the long-term safety of the study drug. This will only be done if allowed by the law.

If you stop taking part in the study but do not withdraw your authorization, your personal information will continue to be used in accordance with this Privacy Supplement and applicable law. No new information or samples will be collected about you or from you by the study team, unless you have agreed to provide them.

If you decide to withdraw your authorization:

- You will no longer be able to participate in the study;
- No new information or samples will be collected about you or from you by the study team;
- The study team may still need to report any safety event that you may have experienced due to your participation in the study to the Sponsor;
- Your personal information, including Coded Information, that has already been collected up to the time of your withdrawal will be kept and used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of the study drug, to satisfy legal or regulatory requirements, and/or for any other purposes permitted under applicable data protection and privacy laws;

- Your personal information (including Coded Information) will not be used for further scientific research. However, if your personal information has been anonymized so that the information does not identify you personally, that information may continue to be used for further scientific research (as described in Section E of this Privacy Supplement), as permitted by applicable law; and
- Biological samples that have been collected but not analyzed will no longer be used, unless permitted or required by applicable law.

You have the additional right to request that any remaining samples that have been collected from you as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. The study team will then send your coded request to the Sponsor. Laws or regulations may require that your samples be destroyed or de-identified if you withdraw from the study, regardless of whether you specifically make such a request.

However, we cannot guarantee the destruction of samples because the sample may no longer be traceable to you, they may have been used up, or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your biological samples and any related data.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ Date _____

Signature of Subject

Use of Biological Samples for Additional Research

The Sponsor 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 or to the disease or condition that made you eligible for 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 participate 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, including 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 the remote possibility that information from your participation in the Additional Research may be disclosed. The Sponsor and study doctors will put measures in place to minimize the possibility that results from this Additional Research could be linked to you.

Testing of DNA and/or RNA: 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 (called "whole genome sequencing"). Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes. The genetic analysis is for research purposes only, and is not a medical test.

This means that the medical importance of the results may not be known, or that they may not be related to any medical condition. The results of tests on your sample will not be given to you, the study doctor, any insurance company, your employer, your family, or any doctor 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. The Sponsor and researchers will put measures in place to minimize the possibility for the results from this research being linked to you, but there is always the remote possibility that information from your participation in the research may be disclosed.

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 learned 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 doctor if you would like to end your participation in the Additional Research.

The study team will give you a Privacy Supplement. It describes what happens to your biological samples and any data generated from them and how they may be used if you withdraw from the Additional Research.

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

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

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

You will not be paid for taking part in this Additional Research. The Sponsor may use information from this Additional Research to develop products or processes, from which the Sponsor could make a profit. There are no plans to pay you or provide you with any products developed from this Additional Research. The Sponsor 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?

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent.

The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

The study team will give you a Privacy Supplement, which is considered part of this Additional Consent Request. The Privacy Supplement tells you about:

- What personal information may be collected from you during the study;
- How your personal information will be used and by whom (including by the study site, the Sponsor, and others outside the study site);
- How your biological samples will be handled;
- How your personal information might be used for other research;
- How your personal information will be protected during transfer;
- Your data protection rights, and whom you may contact about these rights or any related concerns or complaints; and
- What happens to your personal information if you decide to stop taking part in the study.

The Sponsor may share the samples and data from the samples with third parties (such as other researchers and collaborators at institutions and companies) in order to perform the Additional Research described above.

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. The Sponsor does not plan to give any information generated during the Additional Research to you, the study doctor, your personal doctor (if your personal doctor is different from the study doctor), your family, your employer or any insurance company.

9. Contact Information

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

10. Decision to Participate in Additional Research

Below please initial your choice regarding whether to take part in the Additional Research. Thank you for considering whether to participate.

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

Signatures

Agreement to Participate and to Process Data	Participant Initials
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this Additional Consent Request. I have had enough time to review this Additional Consent Request. I also have had an opportunity to ask questions and to decide whether or not to participate.	
2. I understand that participating in the optional collections and/or uses described in this Additional Consent Request is voluntary.	
3. I have read and understand the Privacy Supplement. I understand that my personal information will be processed (including collection, use, transfer, storage, analysis and reporting), as explained in the Privacy Supplement. I understand and agree to the processing of my personal information (including my samples) within and outside my country of residence for health care, medical research, and/or regulatory purposes.	
4. I understand that if I agree to take part, I am free to withdraw my consent to the processing of my personal information (including my samples) in the research described in this Additional Consent Request at any time without giving any reason, without my regular medical care or legal rights being affected. However, even if I withdraw my consent to processing, my personal information held at that time may be kept to comply with laws and regulations and to preserve the integrity of the study or other research done. I also understand that my samples may not be able to be destroyed because they may no longer be traceable to me, may have already been used, or may have been given to a third party.	
5. I do not give up any of my legal rights by signing this Additional Consent Request. I have been told that I will receive a signed and dated copy of this document.	

Printed name of participant

Signature of participant

Date of signature§

PERSON OBTAINING CONSENT

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion†

Date of signature

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.