INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY FOR PARTICIPANTS WITH OBESITY - PART D ONLY

Sponsor / Study Title:	**Pfizer, Inc. / "A MULTI-PART, PHASE 1 STUDY WITH RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO-CONTROLLED, SINGLE- AND MULTIPLE-DOSE ESCALATION TO EVALUATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF PF-07976016 IN HEALTHY ADULT PARTICIPANTS"**
Protocol Number:	**C5541001**
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INTRODUCTION

You are here today as a possible participant in a drug research study sponsored by Pfizer Inc. Taking part in this study is voluntary (your choice). The study staff will be available to answer questions before, during, and after the study.

The sponsoring company (the company paying for this study), Pfizer Inc, employs the study investigator conducting this study.

If you are not completely honest about your health history, you may be harmed by being in this study.

PURPOSE OF THE STUDY

PF-07976016 will be referred to as the "study drug" in the rest of this consent document.

The purposes of this part of the study are:

- To see how a new drug under study is tolerated, if there are significant side effects, and how people with obesity taking Saxenda (liraglutide) feel after multiple oral (by mouth) doses of study drug
- To measure how much of the study drug is in your blood after taking single and multiple oral doses while on Saxenda
- To check the effect of multiple oral doses of the study drug on substances in the body involved in showing and/or regulating the amount of sugar in the blood after an oral glucose tolerance test (OGTT)
    - These substances include:
        - Glucose
        - Insulin
        - C-Peptide

- To measure the amount of Saxenda in your blood after daily injection while taking multiple oral doses of study drug
- To see if the study drug has an effect on your body weight after multiple oral doses taken with liraglutide
- To see if the study drug has an effect on the following after multiple oral doses taken with Saxenda:
    - GLP-1 (a hormone that causes insulin secretion)
    - GIP (a hormone that causes insulin secretion)
    - Glucagon (a hormone that increases blood sugar levels)
    - Fasting glucose
    - Fasting insulin
    - HOMA-IR (insulin resistance)

The study drug is a new investigational drug being studied to supplement diet and exercise for weight management. It is intended for people who are overweight with at least one weight-related medical condition or who are obese. "Investigational" means that the drug has not been approved by the United States (US) Food and Drug Administration (FDA). Study drug and placebo will be given as a liquid which you will drink, or a tablet(s) which you will swallow whole.

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

Saxenda will also be given in this part of the study. Saxenda is an approved marketed drug. It is used by certain overweight people, such as those who are obese or have weight-related medical problems. However, the use of Saxenda in this research study is investigational. Saxenda is a subcutaneous (SC – injected under the skin) injection once a day.

ABOUT THE STUDY

Number of Study Participants

There will be about 18 people joining this part of the study.

Length of Study for Participants

You will be in this study for about 77 days. This does not include the time between screening and dosing, which can be up to 28 days.

This part of the study involves:

- 1 outpatient run-in period (4 weeks) with 4 outpatient visits to the Clinical Research Unit (CRU)
- 1 dosing period during 1 continuous admission. 25 overnight stays at CRU. You will not be able to leave the CRU during that time
- 1 follow-up visit to the CRU about 7 days after the last dose
- 1 follow-up phone call about 4 weeks after the last dose

Eligibility to Participate in Another Drug Study

Your eligibility to take part in another study depends on information from this study. You may be eligible to receive a different study drug in another study as soon as 30 days after your last dose of study drug in this study. This is true for most drugs. Some drugs may stay in your body longer which means that you may have to wait longer before joining another study. These results are usually known after your last blood sample is tested. We will tell you this as soon as possible. We will also tell you if there is a longer than usual period of time that you should not be in another drug study after this one. Our goal is to keep you from doing anything that might potentially harm you.

Dosing Plan

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

The dose of study drug in this part of the study will be determined based on information from the previous dosing groups.

Dosing is planned as follows:

DOSING GROUP	NUMBER OF PARTICIPANTS	STUDY DAYS					
		Outpatient				Inpatient	
		-35 to -29	-28 to -22	-21 to -15	-14 to -8	-7 to -1	1 to 14
1	18	0.6 mg Saxenda	1.2 mg Saxenda	1.8 mg Saxenda	2.4 mg Saxenda	3 mg Saxenda	3 mg Saxenda + TBD* mg study drug or placebo

*TBD – to be determined. Dosing for this part of the study will be based on data from the earlier dosing groups.

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

You have about a 1 in 3 chance of being on placebo during the study.

On study Day -35, you will visit the CRU for your first injection of Saxenda. It will be given to you by a qualified member of the study staff. Saxenda is given in the abdomen, upper thighs, or upper arms. You will be instructed on how to self-administer Saxenda at home during the 4 week run-in period. You will be given sufficient supplies for dosing at home and instructions about food and beverages relative to the timing of your once daily injections. You will also be instructed on how to store the medication. You will be given a dosing diary to record the dosing time of each dose given at home. You will return to the CRU every week during the outpatient run-in period (Study Days -28, -21, and -14). You will bring your completed dosing diary with you at the time of these visits. During these visits, Saxenda will be administered by the CRU staff and you will be given sufficient supplies for dosing at home.

On Study Day -7, you will be admitted to the CRU to continue Saxenda dosing before beginning dosing with study drug or placebo on Study Day 1. Saxenda doses while in the CRU will be given by the study staff, including Day -7 when you check in for the study. You will continue to receive a daily injection of Saxenda through Day -1 of the study.

On Day -1 you will fast overnight for at least 10 hours before an OGTT. It will be done at about the same time as scheduled for Day 8.

From Days 1 to 14, you will continue to receive Saxenda as a daily injection and you will also receive oral doses of study drug or placebo. On Days 1 – 7 and 9 - 14, you will fast overnight for at least 10 hours before receiving a standard breakfast. Breakfast will be provided about 30 minutes before dosing. It should be completely eaten within 20 minutes. Dosing will take place about 10 minutes after completing breakfast. Saxenda dosing will be within 5 minutes of study drug or placebo dosing.

On Day 8, you will fast overnight for at least 10 hours before receiving a single oral dose of study drug or placebo. About 30 minutes after dosing, an OGTT will be done. The timing of the OGTT may be changed based on the study drug blood levels from earlier in the study.

An OGTT involves drinking an 8 oz solution containing 75 grams of sugar. It measures how well the body can break down sugar. A blood sample is taken before drinking the solution and approximately 2½ hours after. During this time period, blood samples will be collected approximately every 30 minutes.

Both you and the study staff will not know whether you are receiving the study drug or placebo. In case of a medical emergency, the study investigator can find out what you have received if considered necessary.

The doses of study drug and placebo that you receive may be compounded in our pharmacy for use in this part of the study. Compounded means that the ingredients are added together and mixed to make the final dose(s).

All oral doses will be taken with water. The total fluid volume of doses and water will be about 8 oz (1cup). All doses must be completely swallowed. We will check your mouth after each dose to make sure the study drug or placebo have been swallowed

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

Study Process

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

Screening

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

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

- Give your race, age, gender, and ethnicity
- Give your medical history
    - You must review and confirm the information in your medical history questionnaire
- Give your drug, alcohol, and tobacco use history

- Give your past and current medication and treatment history. This includes any over-the-counter or prescription drugs, such as vitamins, dietary supplements, or herbal supplements, taken in the past 28 days
- Height and weight will be measured
- Physical exam will be done
- Vital signs (blood pressure and heart rate will be measured)
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- You may be tested for COVID-19
    - COVID-19 testing will be done by collection of a swab sample
- Safety lab tests will be done from blood and urine samples. In addition:
    - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
    - Blood tests to see how your blood clots
        - Fibrinogen
        - PT/INR/aPTT
    - Blood tests for amylase and lipase (enzymes that help with digestion)
    - Blood tests for a lipid (fats) panel
        - Total cholesterol
        - Triglycerides
        - HDL
        - Direct HDL
    - Blood tests to check your thyroid function
        - TSH
        - Free T4
    - Blood test for hemoglobin A1c (HbA1c)
    - Urine to test for drugs of abuse (illegal and prescription)
    - Urine tests to check your albumin/ creatinine ratio
    - Females who have not had a period for at least 12 months in a row will have a blood hormone test to confirm they cannot have children
- You will complete the Columbia Suicide Severity Rating Scale (C-SSRS)
    - This is a scale to assess if a person is thinking about suicide or is exhibiting suicidal behaviors
- You will complete the Patient Health Questionnaire-9 (PHQ-9)
    - This a scale to assess depressive symptoms
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed (males only)
- You will be asked “How do you feel?”

HIV and Hepatitis Testing

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

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

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

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

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

During the Study

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

- You will be asked about any updates to your medical history. This includes medication, drug, alcohol, and tobacco use
- Physical exams, including skin exam
    - Photographs of the skin may be taken if the study clinician thinks it is needed. Photographs are photographic images of the skin that the study team may take of you during the study. You will not be identified in these photographs. However, if you have any markings on the area of your skin photographed, like a tattoo, those markings may appear in the photographs. Pfizer will own these photographs. The photographs will be used and shared along with your study records, as described in this consent document. In addition, the photographs may be used in publications, presentations, brochures, or other ways. The photographs may be used along with text, graphics, or audio materials. You will not be identified by name in any use of the photographs. By signing this consent document, you are giving permission for the study staff to take these types of photographic images and for the uses described above.
- The use of proper birth control will be confirmed/reviewed (males only)
- Vital signs. Your oral temperature may also be measured
- Weight will be measured
- ECGs will be collected
    - It may be necessary to shave or trim hair on your chest so that the patches for the ECGs will stick to your skin
    - Your chest may be marked with a pen to identify the correct areas for ECG patch placement
- You will be asked: "How do you feel?" each day
- An intravenous (IV) catheter may be placed in a vein in one of your arms for blood collection
- OGTTs will be done
- The study investigator may decide to do an alcohol breath test at any time
- You may be tested for COVID-19
- Blood and urine samples will be collected at various times throughout the study
    - Safety Labs: The blood and urine samples will be used for safety labs including the following:
        - Urine samples to test for drugs of abuse
        - Blood tests for Fibrinogen
        - Blood tests for PT/INR/aPTT
        - Blood tests for lipid panel, amylase, lipase, TSH, and free T4
        - Blood tests for HbA1c

- Any leftover urine, serum or plasma (components of blood) taken during the study may be stored and used to assess exploratory safety biomarkers or unexpected safety findings or for other exploratory purposes, including genetic analysis
  - Biomarkers are natural substances in your body that can be used to show how your body works
  - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
- Study Drug Levels: Blood samples will also be used to measure the levels of study drug and Saxenda
  - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for the following:
    - Metabolite identification
    - Evaluate safety aspects related to any concerns during or after the study
    - Check the laboratory test which measures the study drug
    - Other internal exploratory purposes
- Biomarkers: Blood samples will also be used to measure biomarkers
  - Plasma glucose
  - Serum insulin and C-peptide
  - Plasma GLP-1, GIP, Glucagon

  Biomarker samples may also be used to:
  - Evaluate safety or efficacy (ability to produce a desired or intended effect) aspects related to any concerns arising during or after the study
  - Check the laboratory tests which measure the biomarkers
  - Other internal exploratory purposes
- Retained Research Samples: Samples of your blood will be collected, stored, and used to learn more about the study drug
  - Biological substances in your samples, including your genes and biomarkers, may be studied
  - These samples may be kept by Pfizer for as long as the samples are useful for scientific research. This may be for many years (no time limit)

- You will complete C-SSRS and PHQ-9 questionnaires
- You will return to the CRU weekly while dosing with Saxenda at home
- Your dosing diary will be reviewed for dosing compliance
- Your Saxenda injection sites will be checked
- You will return to the CRU for a follow-up visit about 7 days after the last dose
- You will receive a follow-up phone call about 4 weeks after the last dose
- For safety reasons we may add procedures at any time during the study to check on your health status

Blood Draws

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

There will be about 59 blood draws during the study. The total amount of blood drawn during the study is about 480 mL. This is equal to about 16 oz or about 2 cups.

For comparison, the standard blood donation is about 16 oz. (2 cups), once in any 56-day period.

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

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

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug or procedure(s) may make you feel unwell or uncomfortable or could harm you. If you do not understand what any of the side effects described below mean, please let us know. The study investigator or study staff will explain them to you.

It is important that you report all side effects that you have as soon as they occur. This is regardless of whether or not you believe they are caused by the study drug or your participation in this study.

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

Study Drug Risks

During this study, you may receive either placebo and/or the study drug. The study drug is not expected to cause significant safety issues at the dose levels planned in this study. You may experience risks or discomforts when taking part in this study, and a summary of potential risks and discomforts will be provided to you (see below).

You may also experience risks or discomforts that are unknown at this time.

The study drug has been given to rats and monkeys for up to 2 weeks. While animal studies do not always predict the side effects that people may experience, the data that has been collected on the study drug to date are summarized here. All noteworthy findings in these animal studies were seen at much higher blood concentrations of study drug than may be tested in this clinical study. The study staff will be carefully monitoring your health and watching for these types of events.

There were no noteworthy effects in the 2-week study in rats.

In the 2-week study in monkeys, at a dose level that is similar to the highest dose that you may receive in this clinical study, some of the animals experienced the following:

- Ate less food and lost weight
- Vomited occasionally
- Had soft feces

These did not affect the health of the monkeys. There were changes in blood and chemical laboratory tests. These were not considered to be serious as the changes were small, and because there were no negative clinical effects.

At the highest dose in monkeys, which was about 2 times higher than the maximum possible dose that anyone may receive in this study, the animals lost a greater amount of weight. At this high dose, the following were seen:

- Larger changes in blood and chemical laboratory tests
- Some changes in the liver and kidney were seen under a microscope

- This was not seen in all animals in this dose group

This means that, at the highest dose, there was some injury to parts of the kidney, and corresponding decreases in kidney function were seen in the blood tests. There was also injury to some parts of the liver, and corresponding changes in liver function blood tests were seen. The study investigator will be monitoring your blood and urine samples and carefully monitoring your health throughout the study.

Across all dose levels in monkeys, a few animals had minor red or pink discoloration of their skin after about 11 days of daily oral dosing with the study drug that was not considered serious.

In a study focused on cardiovascular safety (heart health), where monkeys received study drug, there were no changes in heart rate or blood pressure, even at high doses. There were small changes in an ECG measurement (called QTc), but these changes were not considered serious.

At the starting dose for this clinical study, the level of study drug in your blood is expected to be at least 285 times lower than the dose tested in monkeys where no significant negative effects were seen. At the maximum dose that may be tested in this study, the level of study drug in your blood will not be expected to be higher than at the dose tested in monkeys where no significant negative effects were seen.

There is a possible risk of skin irritation from UV light exposure when taking the study drug. This has not been evaluated in animals. You will be asked to take precautions including avoiding tanning and prolonged sun exposure and should wear sunscreen.

Saxenda Risks

Liraglutide (also known as Saxenda) is a marketed drug that has been approved for use in the USA since 2010 for management of weight in certain overweight people, such as those who are obese or have weight-related medical problems. Liraglutide has been evaluated in many clinical studies, in both participants with Type 2 Diabetes and participants with obesity.

The known side effects of Liraglutide include:

- **Gastrointestinal problems**

The most commonly reported side effects with liraglutide in the clinical studies are gastrointestinal problems such as

  - Nausea
  - Diarrhea
  - Vomiting
  - Constipation

The reactions are usually mild or moderate, occurring during the first weeks of treatment and diminish within a few days or weeks on continued treatment. To reduce the risk of experiencing gastrointestinal side effects, the dose of liraglutide will be gradually increased from a low starting dose.

- **Hypoglycemia (too low blood sugar)**

Since liraglutide is a glucose lowering agent, it has the potential to cause hypoglycemia (please see above). Hypoglycemia is more common when liraglutide is used in combination with insulin or other medications that cause lowering of blood sugar (these medications are not allowed in this study).

- **Pancreatitis**

An association between the use of GLP-1 receptor agonists (including liraglutide) and pancreatitis (inflammation of the pancreas) has been suggested based on case reports received in clinical studies. Acute pancreatitis is a potentially severe condition which often presents with severe abdominal pain (usually accompanied by vomiting). In rare cases bleeding may occur in the pancreas, which can lead to shock and even death. If pancreatitis is suspected liraglutide should be discontinued and your study investigator will decide whether you should undergo additional diagnostic procedures.

- **Acute gallbladder disease**

An increased incidence of cholecystitis has been observed in some patients treated with liraglutide in clinical studies.

- **Suicidal behavior and ideation**

An increased incidence of suicidal ideation has been observed in some participants treated with liraglutide in clinical studies. Within the study you will be monitored for signs of worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

You must tell your study investigator right away if you have any thoughts about hurting yourself.

If you are having suicidal thoughts or feel in crisis, call the study investigator at the telephone number listed on the first page of this form. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.

- **Dehydration and decrease in kidney function**

Cases of acute decreased kidney function have been reported from long term clinical studies with liraglutide and marketed use of liraglutide. Most of the cases were reported together with significant fluid loss caused by severe vomiting and/or diarrhea. Some of the participants already had kidney disease or other risk factors for kidney failure. Significant loss of fluids and salts due to severe vomiting or diarrhea may in rare cases be associated with decreased kidney function in patients who are prone to kidney failure. If you experience severe or prolonged vomiting, you should drink plenty of fluids in order to avoid dehydration.

- **Allergic reactions**

Injection site reactions may occur with injectable drugs. For liraglutide these are usually mild and transient in nature. Allergic reactions have been reported from clinical studies with liraglutide. The allergic reactions are usually mild with symptoms such as rash, hives or itching. Rarely, a severe form of allergic reaction which could be potentially life threatening (anaphylactic reaction) with additional symptoms such as swelling of throat and face and difficulties breathing has been reported with marketed use of liraglutide. If you experience a severe reaction resembling the description of an allergic reaction it is important that you seek medical attention immediately and inform your study investigator as soon as possible.

- **Thyroid C-cell tumors in animal studies**

In life-long studies with liraglutide in mice and rats, an increased number of thyroid C-cell tumors have been observed. Some of these tumors were cancers. It is not known whether liraglutide will cause C-cell tumors or cancer in people.

- **Increased heart rate**
  Increased heart rate has been observed in some participants treated with liraglutide in clinical studies and with marketed use of liraglutide.

- **Other adverse events**
  Headache, upper respiratory tract infections, and malaise have been reported in clinical studies.

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

Until you know how the study drug and Saxenda will affect you, you should use caution by:

- Avoiding stairs
- Not driving a car
- Not swimming or bathing in a tub
- Not working with machinery or at heights

Other Risks

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

All drugs have a potential risk of an allergic reaction. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help right away (by calling 911 or immediately going to an emergency room) if you think you have any of the following symptoms:

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

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations (racing heart)
- Chest discomfort/tightness
- Muscle pains/stiffness

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

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain

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

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

Additional Risks or Discomforts

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

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

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

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

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

- Life insurance
- Long term care insurance
- Disability insurance

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

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

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

Blood Samples and IV Catheters (if used)

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

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

- Inflammation of the vein
- Swelling
- Pain
- Nerve damage
- Vein irritation from the fluid or medication being given
- Local swelling due to IV fluid accidentally entering the tissue rather than the vein
- Scarring

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

COVID-19 Testing

Collection of a swab sample may cause:

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

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

If you test positive for COVID-19 while on study, you may not be able to continue in the study. If you have a positive result, it may be reported to the Connecticut State Department of Health and your local department of health. If you have any questions about what information may be reported, please ask the study investigator or study staff.

ECG

Possible side effects from having an ECG include:

- Irritation or rash from the adhesive on the patches

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

Fasting

Fasting could cause symptoms such as:

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

OGTT

Possible side effects from having an OGTT include:

- Bloating
- Nausea
- Upset stomach
- Diarrhea
- Headache

Other

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

Use of Birth Control

Females

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

Females unable to have children

Women in this study should not be able to get pregnant or be breastfeeding. You may take part in this study provided that you meet one of the following:

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

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

Males

You must agree to the following during the study and for at least 90 days after the last dose of study drug:

- Refrain from donating sperm

PLUS either

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

OR

Must agree to use birth control/barrier as detailed below:

- Agree to use a male condom and should also be advised of the benefit for a female partner to use a highly effective method of birth control as a condom may break or leak when having sexual intercourse with a female able to have children who is not currently pregnant

- In addition to male condom use, a highly effective method of birth control may be considered in female partners able to have children of male participants

Highly effective methods of birth control include:

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

PLUS

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

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

Pregnancy-Related Risks

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

- Fertility
- Sperm
- Pregnancy
- Unborn child
- Breastfeeding child

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

You cannot participate in this study if:

- You are a man whose female partner is currently pregnant or planning to become pregnant

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

Pregnancy Follow-Up

If you become pregnant during the study or within 28 days after your last dose of study drug or if your female partner becomes pregnant during the study or within 90 days after your last dose of study drug, please:

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

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

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and diet and activity restrictions (details listed later in this document)
- You must not have any significant medical or psychiatric condition, including recent (within the past year) or active suicidal thoughts or behaviors, as determined by the study investigator, which may put your safety at risk or could have an effect on the study results
- You may be eligible to participate if you have well controlled hypertension or hyperlipidemia (high cholesterol) by either diet or stable doses of 2 or fewer medications
- Your body mass index (BMI) must be between 30 – 40 kg/m^2
- You may be asked to provide documentation of your childbearing status
- You must be eligible to be prescribed Saxenda, and willing to self-administer according to the approved label
- You must not have a history of phototoxicity or photosensitivity
- You must not have a current or past diagnosis of type 1 or type 2 diabetes mellitus
- You must not have a personal or family history of medullary thyroid cancer (MTC) or multiple endocrine neoplasia, type 2 (MEN2), or suspected MTC as determined by the study investigator
- You mut not have active/current gallbladder disease
- You must not have acute pancreatitis or a history of pancreatitis in the 12 months before the screening visit
- You must not have a major depressive disorder or other sever psychiatric disorders (for example, schizophrenia or bipolar disorder) within 2 years before the screening visit
- You must not have any history of a suicide attempt in your lifetime
- You must not take any medications (including over-the-counter medications, such as medications for cold or allergies, antacids, herbal supplements, minerals, or vitamins) that are inhibitors or inducers of certain enzymes or proteins within 14 days plus 5 half-lives before the first dose or at any time during the study
    - The study investigator or study staff will review a list of these medications and substances with you
    - Before taking any drugs other than the study drugs, you must call the CRU for approval. It must first be approved by the study investigator

  - You must tell the study staff about any drugs taken during the study
  - Use of certain medications that are unlikely to interfere with the study results may be allowed but the dose of these background medications should stay the same during the study.
- You must not have taken any medications, dietary or herbal supplements that are sensitive CYP3A, BCRP, P-gp/MDRI, OATP1B, or UGT1A1 and UGT1A4 substrates after Day -1 of the study.
  - The study investigator or study staff will review a list of these medications and substances with you
- You must have taken a GLP-1R agonist within 90 days before the first dose of Saxenda
- You must not have a known intolerance or hypersensitivity to Saxenda or other GLP-1R agonists
- You must not take any investigational product (drug or vaccine) within 30 days before the first dose of this study
- You may only participate in one part of this study
- You must not have donated blood for at least 60 days before dosing. Plasma (a component of blood) donation may be allowed
  - You cannot donate any blood or blood products at any time during this study. Donation is not allowed for at least 4 weeks after your last blood draw
- You must not have a history of excessive alcohol use or binge drinking and/or other illicit drug use within 6 months before screening
  - Binge drinking is defined as a pattern of 5 (male) or 4 (female) or more alcoholic drinks in about 2 hours
  - You should not drink more than 14 alcoholic drinks a week
  - A drink is defined as 8 oz. (1 cup) of beer, 3 oz. (6 tablespoons) of wine, or 1 oz. (2 tablespoons) of hard liquor
- You must not be using/taking any drugs of abuse (such as marijuana, cocaine, opioids, etc.). Urine tests will be done to check for such drugs.
  - If a test is positive, you will not be allowed in the study
  - Urine collection may be monitored by a staff member of the same sex
  - You have the right to refuse to be monitored, but may be disqualified from the study
  - While in this study, please do not eat anything that contains poppy seeds. They may cause a positive drug test
- You must not use tobacco or nicotine-containing products in excess of the equivalent of 5 cigarettes or 2 chews of tobacco per day
- You must not use tobacco- or nicotine-containing products for 24 hours before the first dose and while confined to the CRU
- Please let us know if you or a relative are a staff member of Pfizer. If so, you may not take part in this study if you or your relative are supervised by the study investigator or are directly involved with the study

Activity Restrictions

- You will need to stay in the CRU for 24 days starting with check-in
  - You may need to stay in the CRU for longer if you experience a longer study drug effect. This is for safety reasons
  - The study investigator or study staff will decide when it is safe for you to leave the CRU
- You must not do any strenuous exercise for at least 48 hours before each blood draw for safety labs. Examples of this include heavy lifting, weight training, or aerobics
  - Walking at a normal pace is allowed

- You may be asked to wear a device (similar to a wristwatch) that can be used to alert study staff in case of an emergency
- You cannot lie down for 4 hours after dosing on days when blood samples for study drug levels are collected, unless needed for study procedures
- You are advised to avoid direct sunlight or any high intensity UV light exposure from your first admission to the CRU through your last follow-up contact with the CRU
    - You should apply sunscreen with a sun protection factor (SPF) of greater than or equal to 50 and wear eye-protective sunglasses

Diet Restrictions

- You must not eat or drink anything except water for at least 10 hours before each safety laboratory test
- You must not eat or drink anything except water for at least 10 hours before collection of the pre-dose blood sample for study drug and other pre-dose blood samples
- You may drink water freely while in the CRU
- You must not eat anything for at least 10 hours before eating breakfast
- If dosing when an OGTT will be done you must not eat anything for at least 10 hours before dosing and/or OGTT
- You must not drink red wine for 7 days before the first dose. Red wine is not allowed through the collection of the last blood sample for study drug
- You must not eat or drink anything with alcohol for 24 hours (or as stated above for red wine) before (each) check-in. Alcohol is not allowed through the collection of the last blood sample for study drug in each period
    - Study staff may check your breath for alcohol. If alcohol is found, you will not be allowed in the study
- You must not eat or drink anything with caffeine for 24 hours before dosing. Caffeine is not allowed through the collection of the last blood sample for study drug in each period
    - Caffeine can be found in different foods and drinks. Some examples include chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything that has grapefruit or grapefruit-related citrus fruits for 7 days before the first dose. These are not allowed through collection of the last blood sample for study drug
    - Examples of citrus fruits that are not allowed are Seville oranges and pomelos
    - Fruit juices and smoothies may also contain grapefruit or these citrus fruits
- Lunch will be provided about 4–5 hours after dosing
- Dinner will be provided about 9-10 hours after dosing
- An evening snack may be allowed about 12-13 hours after dosing
- If it is necessary to split doses and dose twice a day, the timing of meals or snacks may be changed
- Meals (breakfast, lunch, dinner, and evening snacks) will be provided at appropriate times on all other study days
    - On non-dosing days while in the CRU, meals and evening snacks will be provided at about the same time as when given on dosing days

Possible Benefits of the Study

This study is for research purposes only. There may be no direct benefit to you from taking part. However, information learned from this study may benefit other people in the future.

Alternatives to Participating in this Study

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

Confidentiality

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

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

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

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

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

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

Your personal information will be accessed by:

- The study investigator and other study staff members
- Pfizer and its representatives (including its affiliated companies)
- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. FDA and authorities in other countries)
- Advarra Institutional Review Board (IRB), the IRB that reviewed this study and any other committees responsible for overseeing the research

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

- Determine if you are eligible for this study
- Provide you with reimbursement, as allowed by the study, for your time, effort, and certain expenses related to your participation
- Verify that the study is conducted correctly and that study data are accurate
- Answer questions from IRB(s) or government or regulatory agencies
- Assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process

- Contact you during and after the study (if necessary)
- Follow-up on your health status, including using publicly available sources (for example, public databases or the internet) should the study staff be unable to contact you using information held on file
- Protect your vital interests such as providing information to an emergency department of a hospital if you are being treated
- Answer your data protection requests (if any)

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

- Emergency contact information
- Details of family medical history

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

Text Messages

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

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

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

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

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

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

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

Your Coded Information will be used by the following:

- Pfizer and its representatives (including its affiliated companies)

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

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

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

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

How are my biological samples handled?

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

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

Yes. Pfizer may use your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of this study, to support and advance other scientific research projects, including improving the quality, design, and safety of other research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products, and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable

safeguards will be used to protect your Coded Information, biological samples, image and/or audio/video recordings used in any future research and may include:

- Limiting access to individuals bound by duties of confidentiality
- Taking steps to minimize the risk that you could be re-identified
- Obtaining approval of ethical review boards

Furthermore, if your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, have identifiers removed such that they can no longer be readily identified with you, they may be used for future research purposes.

Study-Related Injuries

You will also receive a card with information about this study. This information includes:

- The name or number of the study
- The CRU 24-hour phone number

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

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

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

To help avoid injury, it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.
You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. A 24-hour answering service is available.

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

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

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

Legal Rights

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

Whom To Contact About This Study

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

- Whom to contact in the case of a research-related injury;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedure;

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

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

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00074312.

Link to Additional Information

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

Payment for Taking Part in the Study

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

You may be eligible for a travel and hotel bonus payment:

- $0.20/mile per one-way trip to or from the CRU based on your home address
- For participants traveling long distances, a 1-night hotel stipend ($150.00) for the night prior to your visit(s), if needed

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

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

U.S. Citizens: Payments may be considered taxable income. If you receive $600.00 or more in taxable payments within a calendar year, your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1099). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 24% and receive a tax form (1099). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

Non-U.S. Citizens: Payments may be considered taxable income. Your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1042-S). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 30% and receive a tax form (1042-S). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

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

- You will not be allowed to be in this study
- You may not be allowed to be in any future studies

Screening Payments

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

Screening Visit at CRU	$175.00

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

Study Payments

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

- If you do not follow instructions (including those listed in the New Haven CRU House Rules), if you are late for blood draws, or if you miss procedures, your payment may be reduced. You will be paid a prorated amount based on the extent of your participation if:
    - You are not able to complete the study
    - You choose to leave the study
    - You are withdrawn from the study early by the study investigator for non-safety-related issues
    - The study is stopped early
    - You are qualified but not chosen to participate
- You will not be given the study completion bonus if you drop out of the study early

- Partial payments are planned during the study. Details will be provided at screening
- A final payment will be provided to you within 2 weeks of finishing the study
- Pfizer may use information resulting from the study or samples collected in the study to develop products or processes. Pfizer may make a profit from these. There are no plans to pay you or provide you with any products developed from this research. Pfizer will own all products or processes that are developed using information or samples from the study

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

STUDY PARTICIPANTS			
Type of Activity	**Payment per Activity**	**Total Number (Days/Weeks)**	**Total**
Overnight Stay	$250.00	25	$6,250.00
Time from first dose of Saxenda to admission	$15.00	28	$420.00
Duration of Follow-Up Period (Discharge to Follow-Up Call)	$15.00	24	$360.00
Follow-Up Visit to CRU	$250.00	5	$1,250.00
Follow Up Phone Call	$100.00	1	$100.00
Procedures at Home	$75.00	28	$2,100.00
Completion Bonus	$1,926.00		$1,926.00
Total Payment Part D	$12,406.00		

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

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

Costs for Study Participants

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

Your Decision to be in the Study

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

- You do not follow the instructions of the study investigator
- We find out you should not be in the study

- The study is stopped
- The study becomes harmful to your health
- You do not follow the New Haven CRU House Rules

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

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

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

New Findings

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

AGREEMENT TO BE IN THE STUDY **PIMS # _____**

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

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

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

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

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

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

- You will get a copy of this signed and dated ICD for your records
- You agree to participate in this study
- It is your responsibility to tell the study investigator about all changes in your physical or mental health during the study

Printed Name of Adult Study Participant (Name as appears on U.S./State Government-Issued ID)

Signature of Adult Study Participant Date

Printed Name or Initials of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent Date