INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

Sponsor / Study Title:	**Pfizer Inc / "A PHASE 1, RANDOMIZED, OBSERVER-BLIND, DOSE-RANGING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF MODIFIED RNA VACCINE CANDIDATES AGAINST PANDEMIC INFLUENZA IN HEALTHY INDIVIDUALS 18 THROUGH 49 YEARS OF AGE"**
Protocol Number:	**C5561001**
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INTRODUCTION

You are here today as a possible participant in a vaccine 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.

If you are a general employee of this research center (you cannot be an employee working directly on this vaccine), you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

PURPOSE OF THE STUDY

PF-07985819 will be referred to as the "study vaccine" in the rest of this consent document.

The purposes of this study are:

- To see how a new vaccine under study, and a marketed influenza (flu) vaccine, are tolerated, if there are significant side effects, and how healthy adult participants feel after receiving these vaccines
- To describe the response of your immune system (the body's natural defense system) to each study vaccine using a variety of blood tests

The study vaccine is a new investigational vaccine called Pandemic Influenza Modified RNA Vaccine (pdmFlu vaccine) being studied to prevent flu. "Investigational" means that the vaccine has not been approved by the United States (U.S.) Food and Drug Administration (FDA).

Study vaccine, Licensed Quadrivalent Influenza Vaccine (QIV) and placebo will be given by intramuscular (IM, into the muscle) injection.

The placebo looks like the study vaccine but does not contain any active ingredients. The placebo is used in this study only to maintain the blind, since the study vaccine is given in 2 doses and the licensed QIV is a single dose.

Licensed QIV will also be given in this study. This is the most recently approved/marketed flu vaccine. The U.S.-licensed QIV intended to be used in this study is Flucelvax. However, the use of Flucelvax in this research study is investigational.

ABOUT THE STUDY

Number of Study Participants

There will be up to 60 people taking part in this study.

Length of Study for Participants

You will be in this study for up to 7 months. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

- 2 dosing periods
- 7 visits to the Clinical Research Unit (CRU) (8 visits if screening visit is on a different day than first dosing)
    - 2 of these visits are for dosing
    - 5 of these visits are for follow-up

Each visit to the CRU will last at least 2-4 hours. You will be unable to leave the CRU during that time.

Eligibility to Participate in Another Drug Study

Your eligibility to take part in another study depends on information from this study. You are not eligible to take part in another study during participation in this study. Our goal is to keep you from doing anything that might potentially harm you.

Dosing Plan

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

The dose of study vaccine will start at 30 µg. The highest dose planned for this study is 90 µg. The dose will only increase if it is believed to be safe. How well the study vaccine is tolerated, and blood tests will help us to decide if it is safe.

Up to three groups of 20 participants are planned.

Dosing is planned as follows:

DOSING GROUP	NUMBER OF PARTICIPANTS	STUDY VISIT	
		1	3
1	20	30 µg study vaccine or licensed QIV	30 µg study vaccine or placebo
2	20	60 µg study vaccine or licensed QIV	60 µg study vaccine or placebo
3	20	90 µg study vaccine or licensed QIV	90 µg study vaccine or placebo

You will receive a single IM injection at study visits 1 and 3. Injections will be given in the deltoid muscle (muscle located in the upper arm) of one of your arms.

If you receive study vaccine at Study Visit 1, you will also receive it at Study Visit 3. If you receive QIV at Study Visit 1, you will receive placebo at Study Visit 3.

There will be at least 18 days between each injection.

Some of the dose(s) that you receive is/are compounded in our pharmacy for use in this study. Compounded means that the ingredients are added together and mixed to make the final dose(s).

It will be randomly assigned, like the flip of a coin, who receives study vaccine, QIV, and placebo. You have about a 1 in 4 chance of receiving QIV at Visit 1 and placebo at Visit 3.

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

This is a research study. The study vaccine or QIV 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 vaccines taken in the past 60 days and 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, heart rate, and temperature will be measured)
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- Safety lab tests will be done from blood and urine samples. In addition:
    - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
    - Urine to test for drugs of abuse (illegal and prescription)
    - Females able to have children will have a urine or blood pregnancy test
- A rapid antigen test for flu will be conducted by collection of a swab sample
    - This is to see if you currently have the flu
- You will be asked for information about your flu shot from last season, if received
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed
- You will be asked "How do you feel?"

HIV and Hepatitis Testing

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

HIV is the virus that causes acquired 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, vaccines, alcohol, and tobacco use
- Physical exams may be done
- The use of proper birth control will be confirmed/reviewed
- Vital signs
- 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 to minimize activity while attached to the monitor
- You will be asked: "How do you feel?" at each visit
- The study investigator may decide to do an alcohol breath test at any time
- Rapid antigen tests for flu will be conducted
- Blood and urine samples will be collected at various times
  - Safety Labs: The blood and urine samples will be used for safety labs including the following:
    - Urine samples to test for drugs of abuse
    - Urine or blood samples for pregnancy testing (females able to have children)
    - Blood samples will also be used to measure your immune response and peripheral blood mononuclear cells (PBMCs) isolation
      - PBMCs are a certain type of white blood cells
- You will be observed for about 30 minutes after each study vaccination
- You will return to the CRU for follow-up visits and your second study vaccination
  - There will be a follow-up visit about 1 week after your first study vaccination
  - You will receive your second study vaccination at least 18 days after your first vaccination
  - There will be follow-up visits after your second study vaccination at 1 week, 4 weeks, 3 months, and 6 months
- For safety reasons we may add procedures at any time during the study to check on your health status

Blood Draws

You must provide biological samples in order to take part in this study. Blood samples will be taken by individual needlesticks from a vein in your arm. Additional samples may be collected depending on the results of your laboratory tests or if a replacement sample is needed.

There will be up to 8 blood draws during the entire course of the study. The total amount of blood drawn is up to 572 mL. This is equal to about 19 oz., or about a little less than 2½ cups.

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

These samples will be used to measure your level of antibodies, and to isolate PBMCs to understand your response to the study vaccine.

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

Study Vaccination e-Diary

On the day of your study vaccination, you will download an e-diary app to your smartphone or tablet. The e-diary has questions related to possible side effects you may experience following the study vaccination. The e-diary is secure, and your confidentiality will be maintained.

You will be given a thermometer to take your temperature (under your tongue) and a device to measure any redness or swelling on your arm where you get the study vaccination. The study staff will provide training on how to complete the e-diary and use the thermometer and measuring device.

You will need to complete the e-diary questions every day for at least 7 days after each study vaccination. You will start completing the e-diary on the evening of study visits 1 and 3 (study vaccination days) and then complete the e-diary daily for 6 more days after each study vaccination (14 days in total). If you have symptoms ongoing after the 7-day diary period, you will be contacted by site staff to collect information about these symptoms until they resolve, or until you have no symptoms ongoing within 1 month following study vaccination.

Ideally, you should complete the e-diary every day, as the device will limit the time frame in which missed days may be entered.

If you have any severe symptoms after the study vaccination, any redness or swelling that is 21 units or more on the measuring device, severe pain at the injection site, or a temperature of 39°C (102.1°F) or higher, you must contact the study investigator/site staff as soon as possible, and they may schedule an extra visit for further assessments.

Additional Procedures for Monitoring of Potential Myocarditis or Pericarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the BNT162b2 vaccine as described in the next section (Possible Risks and Discomforts). Symptoms include:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

If you experience these symptoms, or if an irregularity is noted on your ECG or laboratory results during this study, site staff will arrange for you to visit a cardiologist (heart specialist) for a check-up. At the check-up you will have an ECG and will be asked to provide a blood sample of approximately 20 mL (about 1½ tablespoons) to check your health. If needed, based on the results of these tests, study staff may also conduct additional heart tests: an echocardiogram (a test that uses ultrasound waves to look at the heart and its movement) and/or a magnetic resonance imaging (MRI) scan, which uses magnetic field and computer-generated radio waves to create detailed images of your heart. Any additional specialist visits will be made at no cost to you.

Possible Risks and Discomforts

Taking part in this study has some risks. The study vaccine or procedure(s) may make you feel unwell or uncomfortable or could harm you. If you do not understand any of the side effects described below, 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 vaccine 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 Vaccine Risks - pdmFlu

The pdmFlu vaccine used in this study is a type of influenza modified RNA (modRNA) vaccine. The full risk profile of the influenza modRNA vaccine is not yet known. Around 24000 participants 18 years of age or older have received an influenza modRNA vaccine at a dose level up to 90 mcg (most younger

adults received 30 mcg and most older adults received 60 mcg). In all studies, individuals who receive modRNA influenza vaccine are checked for side effects. In some studies, blood tests to check the health of internal organs and routine heart tests (ECGs) were done. None of the safety tests that were done raised any concerns.

One participant 65 years old who received influenza modRNA vaccine at a dose level of 60 mcg developed a temporary increased level in a lab test that measures heart muscle damage and changes to their ECG after vaccination, but the participant did not have any symptoms. There was no confirmed diagnosis made after follow-up testing, however this event may have been myocarditis/pericarditis. Myocarditis/Pericarditis is a potential rare risk with this type of vaccine (please see further information below). This event was investigated by the study sponsor, and it was judged safe to continue further vaccinations.

Further study is needed to fully describe the safety profile of influenza modRNA vaccine, however, currently the following risks have been determined to be related to influenza modRNA vaccine:

- Injection site pain
- Injection site swelling
- Injection site redness
- Enlarged lymph glands
- Muscle pain
- Joint pain
- Pain (most frequently described as body aches)
- Headache
- Fatigue (tiredness)
- Chills
- Fever
- Diarrhea
- Nausea.

Since influenza modRNA vaccine is similar to other modRNA vaccines, like those developed to prevent COVID-19 (for example, BNT162b2, Comirnaty), similar risks could be expected. However, in larger enrolled populations, they could occur more or less frequently, and new risks may be identified.

Although influenza modRNA vaccine has been studied in a small group of people thus far, billions of doses of mRNA-based vaccines such as BNT162b2 have been given to hundreds of millions of people worldwide to combat COVID-19.

The following risks have been determined to be caused by the BNT162b2 COVID-19 vaccine:

Very common (occurring in at least 1 out of 10 people):

- Injection site pain
- Injection site swelling
- Fatigue (tiredness)
- Chills
- Fever
- Headache

- Joint aches
- Muscle aches
- Diarrhea.

Common (between 1 in 10 and 1 in 100 people):
- Feeling sick (nausea)
- Being sick (vomiting)
- Injection site redness.

Uncommon (between 1 in 100 and 1 in 1,000 people):
- Enlarged lymph glands
- Allergic reactions (symptoms may include rash, itching, hives, and swelling of the face and lips)
- Decreased appetite
- Lack of energy
- Sweating
- Night sweats
- Pain in arm
- Feeling weak or unwell
- Injection site itching
- Difficulty sleeping (insomnia).

Rare (between 1 in 1,000 and 1 in 10,000 people):
- Drooping of the face (acute peripheral facial paralysis).

Very rare (less than 1 in 10,000 people):
- Inflammation of the heart muscle (myocarditis)
- Inflammation of the lining outside the heart (pericarditis).

Frequency that cannot be estimated from available data:
- Severe allergic reaction (anaphylaxis)
- Facial swelling in vaccine recipients with a history of injection of dermatological fillers
- Pins and needles (paresthesia)
- Reduced sensation of touch (hypoesthesia)
- Erythema multiforme (symptoms include red spots or patches that may resemble a target or bullseye with a dark red center surrounded by paler red rings)
- Heavy menstrual bleeding
- Extensive swelling of the vaccinated arm.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the BNT162b2 COVID-19 vaccine. Cases have mainly been reported in younger men after the second vaccination dose, however, there have been some cases reported in older men and women and after the first vaccination dose and booster doses. The chance of having this occur is very low and, in most of these people, symptoms began within 14 days of vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath

- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff if you have any of these symptoms. They may arrange for some tests to investigate further.

Available data shows most cases have been mild and tend to recover within a short time. Some cases require intensive care support and fatal cases have been seen. Data also shows that the short term (less than 3 months) course and outcome of myocarditis and pericarditis following vaccination is milder than myocarditis or pericarditis in general. Rates of myocarditis and pericarditis after booster doses do not appear to be higher than after the second dose in the primary series.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor.

The pdmFlu vaccine may involve risks that are currently unknown; therefore, it is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause influenza disease (flu).

QIV (Flucelvax) Risks

Flucelvax is a commercially available vaccine and typically administered to you or your child 6 months of age and older to help protect against flu. This vaccine uses killed virus and none of the ingredients in the vaccine can cause flu.

When a person is given QIV, the immune system will produce its own protection (antibodies) against the disease.

The QIV is intended to protect you against the four strains of virus contained in the vaccine about 2 to 3 weeks after the injection. In addition, if you are exposed to flu immediately before or after your vaccination, you could still develop the illness as the incubation period for flu is a few days. The vaccine will not protect you against the common cold, even though some of the symptoms are similar to flu.

Like all medicines, this vaccine can cause side effects, although not everybody gets them. The following effects have been reported with this licensed flu vaccine:

General symptoms may include:

- Rash
- Itching
- Hives
- Redness
- Difficulty breathing
- Shortness of breath
- Swelling of the face, lips, throat, or tongue
- Cold, clammy skin
- Palpitations (racing heart)
- Dizziness
- Weakness

- Fainting

Other side effects reported in adults:

Very common (may affect more than 1 in 10 people):

- Headache
- Myalgia (muscular pain)
- Fatigue
- Rash
- Reactions at the injection site:
  - Pain
  - Erythema (redness)
  - Swelling
  - Induration (hardness)

Common (may affect up to 1 in 100 people):

- Loss of appetite
- Nausea
- Diarrhea
- Vomiting
- Arthralgia (joint pain)
- Chills
- Ecchymosis (bruising)

Uncommon (may affect up to 1 in 1,000 people):

- Fever

Frequency unknown:

- Allergic reactions
- Abnormal perception of touch
- Pain
- Paresthesia (tingling, numbness, or burning)
- Swelling
- Urticaria (rash or hives)
- Pruritus (itchy skin)

Guillain-Barre Syndrome (a rare but serious condition affecting the body's nervous system)

Until you know how the study vaccine 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 vaccine 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 or shortness of breath
- Wheezing
- Difficulty swallowing
- Swelling of the face, mouth, lips, gums, tongue, throat, or neck

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations
- 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

Blood Samples

- 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
- Scarring

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

Flu Testing

Collection of a swab sample may cause:

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

ECG

Possible side effects from having an ECG:

- 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.

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 not able to get pregnant include women who:

- 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. If you are under the age of 60, you will have a blood hormone level confirming that you cannot get pregnant

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

Females able to have children

If you are sexually active, you must use a highly effective method of birth control. The birth control must be used consistently and correctly from the start of dosing (earlier for hormonal birth control), during the study, and for at least 28 days after the last dose of study vaccine.
Acceptable 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
- Sexual abstinence – defined as refraining from heterosexual intercourse and is the preferred and usual lifestyle of the participant

Other Effective Methods of Birth Control

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

Males

You must agree to the following during the study and for at least 28 days after the last dose of study vaccine:

- 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

You must agree to use birth control/barrier as detailed below:

- Agree to use a male condom when having sexual intercourse with a female able to have children who is not currently pregnant

OR

- Have had a vasectomy, with the absence of sperm having been confirmed

Pregnancy-Related Risks

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

- 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 vaccine 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 currently pregnant, planning to become pregnant, or are breastfeeding a child
- 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/your partner becomes pregnant during the study or within 28 days after your last dose of study vaccine, please:

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

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

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and activity restrictions (details listed later in this document)
- You must not have any significant medical or psychiatric condition, as determined by the study investigator, that may put your safety at risk or could have an effect on the study results
- You may be asked to provide documentation of your childbearing status
- You must be willing to abstain from strenuous or endurance exercise through visit 4 of the study
- You must not have a history of severe adverse reaction associated with any vaccine and/or severe allergic reaction (for example, anaphylaxis) to any component of the study vaccine

- You must not have a compromised immune system with known or suspected deficiency of your immune system
- You must not have a history of autoimmune disease (your immune system attacks your body) or an active autoimmune disease requiring treatment
    - The study staff will review a list of these diseases with you
- You must not have any condition associated with prolonged bleeding that might affect your ability to receive an IM injection
- You must not have a prior history of heart disease, including prior diagnosis of coronary artery disease, myocarditis, pericarditis, uncontrolled high blood pressure, or heart failure
- Hormonal birth control (detailed earlier in this document) is allowed
- Unless considered medically necessary, no vaccines other than the study vaccines should be given within 14 days before the first study vaccine and 14 days after the second study vaccine
- If enrolled in dosing groups 1 and 2, you must not have had any modRNA vaccines within 28 days before the first study vaccine and 28 days after the second study vaccine. If enrolled in dosing group 3, you must not have had any modRNA vaccines within 60 days before the first study vaccine and 60 days after the second study vaccine.
- You must not have had any other (non-study) flu vaccine within 6 months (175 days) before the first study vaccine through completion of the study
- You must not have received any chronic medications with known systemic immunosuppressant effects, radiotherapy, or cytotoxic agents (cancer treatments) within 60 days before study enrollment through the end of the study
- You must not have received systemic corticosteroids (greater than 20 mg/day of prednisone or equivalent) for greater than or equal to 14 days from 28 days before enrollment in the study through 28 days after the last study vaccine
- You must not have received a blood or plasma (a component of blood) products or immunoglobulins (proteins) within 60 days before study enrollment through the end of the study
- You must not take medications that prevent fever, or other pain medication to prevent symptoms associated with the study vaccines
    - You may be allowed to take such medications if you are taking them for a medical condition
- You must not be participating in other studies involving receipt of an investigational product within 28 days prior to study entry and/or during study participation
- 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 cocaine, opioids, etc.). Urine tests will be done to check for such drugs.
    - If a test is positive for anything other than cannabinoids, 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
- 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 should avoid strenuous or endurance exercise through Study Visit 4, for example hiking uphill or with a heavy backpack, high-intensity muscle-strengthening activity (like resistance or weights), running, swimming laps, aerobic dancing, heavy yardwork such as continuous digging or hoeing, tennis (singles), cycling 10 miles per hour or faster, or jumping rope

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).
- **Data captured from electronic devices**
    - eConsent tablet if used to complete the consent process
        - 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
    - e-Diary
        - This information may include:
            - Injection site reactions
            - Other side effects
            - Daily temperatures
    - Mobile applications and other digital tools used in the study may have their own privacy policies. Those policies provide additional information about the data processing activities performed.

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. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

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 vaccine
  - Understanding the study and the study results and learning more about modRNA vaccines
  - Assessing the safety of the study vaccine
- **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 vaccine
    - 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 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 future 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 institutional 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.

Your biological samples will be used only for scientific research. Each sample will be labeled with a code so that laboratory workers testing the samples will not know who you are. Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your genetic material will be performed.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of Pfizer and may be shared with other researchers as long as confidentiality is maintained and no testing of your genetic material will be performed. You will not be told of additional tests, nor will you receive results of any of these tests.

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: Pro00075670.

Link to Additional Information

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

Payment for Taking Part in the Study

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

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	$300.00

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

Study Payments

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

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

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

STUDY PARTICIPANTS			
Type of Activity	**Payment per Activity**	**Total Number (Days/Weeks)**	**Total**
Outpatient Visits (includes screening)	$300.00	7*	$2,100.00
e-Diary Completion (per week)	$50.00	4	$200.00
Additional Procedures (PBMC Draws, etc.)	$100.00	7	$700.00
Total Payment	$3,000.00		

*There may be some participants who complete their screening and first dose as separate visits. In this case, the total number of outpatient visits would be 8, and total for this activity would be $2,400.00, and the total study payment would be $3,300.00.

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

If you have any questions regarding your compensation for participation, please contact the study staff.

Costs for Study Participants

The study vaccine, 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 vaccine 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 Informed Consent Document (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