

Concise Consent Form
INTRODUCTION

You are here to decide whether to join the research study described below. The study is sponsored by Pfizer, Inc. It is up to you whether or not you want to be a part of this study. Please ask questions and discuss this study with anyone you want and take as much time as you need to decide.

Why is this research being done?

We are testing whether a new untried chewable form of a drug called atorvastatin will reach the same levels in your blood and will be as safe as the approved pill form of atorvastatin. Atorvastatin, also called Lipitor®, is an already approved drug used widely to lower cholesterol. We are also comparing two ways of giving written information to people who want to join this study to find out which is easier to understand.

Who can join the study?

You might qualify for this study if you are between 18 and 55 years old and healthy. You may **not** join this study if you:

- Weigh less than 110 pounds or are significantly overweight
- Are pregnant or breast feeding
- Are allergic to any drugs, including statins or have had difficulty taking statins
- Regularly drink more than 7 alcoholic drinks (including beer, wine, hard liquor) a week if you are a woman or more than 14 drinks a week if you are a man
- Use any drugs of abuse
- Smoke more than 5 cigarettes a day.

You may **not** be able to join *at this time* if you:

- Donated blood or blood products in the previous 8 weeks. You will not be able to donate for 4 weeks after the study ends.
- Were in another drug study in the last 30 days.
- Have taken any prescription or over the counter drugs, including vitamins, minerals, or dietary supplements in the last 7 days.
- Have eaten grapefruit or grapefruit products within the last 7 days.
- Have taken hormones for birth control, or hormone replacement therapy or herbal supplements (like St. John's Wort) within the last 28 days.

What do we do to find out if you can be in the study?

We will take a medical history, do a physical exam, take your blood pressure and pulse, do an EKG (a routine test of your heart), and test your blood and urine to see if your kidneys, liver and other organs are working fine. If you are a woman, we will test your urine or blood to make sure you are not pregnant. We will test your urine for illegal drugs. If your drug test is positive, it will be noted in your record and you will not be able to join the study. If you have concerns about the drug testing, you should not join the study.

What will happen during the study?

If you qualify and want to join, you will be in the study for about 3 weeks. During that time, you will stay in the Clinical Research Unit (CRU) for two study periods. During each of these 2 periods, you will stay in the CRU for 4 nights. There will be at least 14 days between period 1 and 2, during which you will be at home and not take any medicines.

During each of the 2 study periods, you will take a study medication. One time you will get atorvastatin as a pill to swallow and the other time you will get the new chewable pills. We will use a random process (like flipping a coin) to decide which one you will get first.

For each of the 2 study periods in the CRU:

1. Please do not eat or drink anything (except water) for 4 hours before you arrive at the CRU. We will draw your blood, review any medications or health problems you have, do a physical exam, and test your urine for illegal drugs.
2. Starting at midnight of the first night of each period in the CRU, you will not be able to eat or drink anything (except water) for 8 hours. In the morning, we will take your blood pressure and pulse and ask you about any symptoms.
3. At 8am, we will give you either 1 pill to *swallow* or 2 pills to *chew* and then ask you to drink a full glass of water. We will check to make sure that you actually do chew or swallow the pill. You will not be able to eat and will have to sit up for 4 hours after getting your pill. We will check your blood pressure and heart rate.
4. We will draw a blood sample 15 minutes after you take the pill, then every half hour 3 times, and then every hour for 3 more samples. Further blood samples will be taken at 6 hours, 9 hours and 12 hours after you take the pill.
5. On the second day, you will have blood drawn at 8am and 8pm. On the 3rd and 4th day, blood will be drawn at 8am. The total amount of blood drawn is about ½ cup. This is less blood than you would give if you were donating blood (about 2 cups).
6. On the 5th day, you will be able to leave. You will return to CRU about 15 days later and everything described above (#1-#6) will be repeated.

While in the study you should tell us about any side effects you have, and call 203-401-0300 to report side effects in between study visits. We will also regularly ask you how you feel. Periodically, we will also test your urine for drugs of abuse. You may be observed by a member of the same sex when giving urine for drug testing.

What responsibilities and restrictions will you have while staying in the clinical research unit?

Before we admit you to the unit, we will ask you to empty your pockets, remove your shoes and hat, and put your belongings on a table. We may pat you down or scan you with a metal detector.

You will be confined to stay in the CRU for 4 nights in study period 1 and then again about 15 days later for another 4 nights in study period 2. We will give you 3 meals a day and an optional bedtime snack while in the CRU except you will not receive breakfast on the day you are given the study medication. Please finish all the food you are given. You will not be able to exercise while in the CRU.

You will **not** be able to drink any alcohol or have any food or beverage containing caffeine starting while you are staying in the CRU. Caffeine is found in chocolate, coffee, tea, cola drinks, as well Dr. Pepper®, Mountain Dew®, and others. There is no smoking in the CRU building. You will also not be able to eat or drink anything with grapefruit, Seville oranges, or pomelos or take any medications not approved by the study doctor until the study is over.

What are the risks of being in this study?

This is the first time that the chewable form of atorvastatin will be given to people. Therefore, all of the side effects are not known. There may be side effects- even serious or life threatening ones- that we do not yet know about. For your safety, please tell the study staff about any side effect you think you are having.

Many people have taken the approved form of atorvastatin (Lipitor®). Side effects that have been reported include:

Constipation, diarrhea, gas, heartburn,
Fatigue and headache
Pain in the abdomen, back, muscles, or joints and headache
Rarely, liver and muscle damage.

If you have any side effects, we may measure your blood pressure, monitor your heart, and monitor the amount of oxygen in your blood with a clip on your finger. We may draw additional blood or do some other tests. We may give you fluids through a vein in your arm or medications to treat your side effects.

Some people have pain, bleeding, bruising, feel lightheaded, or faint when their blood is drawn.

We will give you **any new information** about risks or other information that becomes available that may affect your willingness to continue in the study.

What are the benefits of being in this study?

This study will not benefit you medically. What we learn may lead to a new chewable pill to lower cholesterol.

What choices do you have other than being in this study?

You do not have to join this research study if you do not want to. If you join, you can quit at any time. If you choose not to join or to quit, it will not affect your regular medical care.

Can your study participation be stopped even if you don't agree?

The study doctor, Pfizer, the committee that reviewed this study (IntegReview), or the Food and Drug Administration can take you out of this study without your permission *if*:

continuing in the study could harm you,
you do not follow study instructions or the CRU house rules, or
the study is stopped.

What about birth control while you are in this study?

Because we do not know the effects of the study drug on unborn fetuses or on sperm, both men and women must avoid pregnancy during the study. The most certain way to avoid pregnancy is to not have sex. If you choose to have sex, you must use an effective method of birth control from the time of the first dose of the study drug until 28 days after the second dose of study drug. If you are a woman and can have children, you **cannot** use hormonal birth control, but **must** use **2** of the following: condoms, diaphragm, spermicidal gels or creams, or tubal ligation. If you are a male and have not had a vasectomy (or have had a vasectomy within the previous 6 months), you **must** use a condom and have your partner use another form of birth control (such as a diaphragm, birth control pills, foam). If you had a vasectomy more than 6 months ago, you should still use a condom to prevent passing the drug to your partner. If you or your partner does become pregnant, we will ask for information about the pregnancy.

Will you be paid?

We will mail you a check for \$X for travel expenses to and from screening, **unless** you test positive for drugs of abuse or for nicotine, or if you leave the screening early.

If you successfully complete the entire study, we will pay you up to \$X for your participation plus a \$X completion bonus for a total of \$X. We will mail you a check about 2 weeks after you finish the study. We will pay you **less than the full amount possible** if you do not follow instructions, are late for or miss blood draws or other tests, or if you do not finish the study. If you are not able to finish the study, are taken off study by the doctor, you choose to leave early, or the study is stopped, we will pay you only part of the money based on how much time you spent.

Who will be able to see your medical information?

We keep clinic records about your health with your name on them, and separate study data-- with a code number but not your name-- about what was done in the study. The following groups of people may see your study data and clinical records during and after the study:

- Employees of Pfizer and of IntegReview- the committee that approved this study;
- Researchers conducting this study at other centers;
- People at the U.S Food and Drug Administration, and
- Accrediting agencies.

Pfizer may use your information for research, legal reasons, or research reports. However, Pfizer will not identify you in any publications, reports, or presentations about this study.

What if you are injured as part of the study?

If you are hurt by being in this study, Pfizer will pay for the necessary medical treatment. Pfizer does not offer any payment for lost wages or other expenses besides medical care. To help avoid injury, please follow all study directions. If you have an injury that you think is related to the research, please call the study doctor immediately at 555-555-5555 (24 hours a day). Please ask the study doctor if you have any questions.

Who can you talk to for more information about this study?

Please contact Dr. Jane Doe at 555-555-5555 (24 hours a day) if you have any questions about this research study. Please contact the Chairperson of IntegReview (the group that approved this study and consent form) at 555-555-5555 or email@internet.com, if you have concerns about your rights as a participant.

Standard Consent Form
INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF COMPANY: Pfizer Inc
CITY AND STATE: Groton, CT

NUMBER AND NAME OF STUDY: A2581175; “AN OPEN LABEL, RANDOMIZED, SINGLE DOSE, TWO-WAY CROSS OVER BIOEQUIVALENCE STUDY COMPARING A NEW 40MG ATORVASTATIN CALCIUM CHEWABLE TABLET TO A 40 MG COMMERCIAL ATORVASTATIN CALCIUM TABLET FORMULATION IN HEALTHY SUBJECTS”

NAME OF STUDY DOCTOR: Jane Doe, MD

ADDRESS OF STUDY SITE: Pfizer New Haven Clinical Research Unit
Address
New Haven, CT XXXXX

TELEPHONE NUMBER 24 HOURS: 555-555-5555

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

INTRODUCTION

You are here today as a possible volunteer in a drug research study sponsored by Pfizer Inc. Whether or not you are in this study is strictly up to you. You may refuse to take part in this research study. The study staff will be available to answer questions before, during, and after the study.

The Sponsoring Company, Pfizer Inc, employs the study doctor conducting this study.

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

INFORMATION ABOUT THE DRUGS

Atorvastatin calcium (Lipitor®) will be referred to as “the study drug” in the rest of this document.

The study drug is a marketed drug used to treat people with high cholesterol. The usual dose of the study drug to treat high cholesterol is 10 mg to 80 mg given once daily. This is a two period study. In one period you will receive a single, oral 40 mg dose of the commercial Lipitor® tablet. In the other period, you will receive a single, oral 40 mg dose of the investigational chewable formulation of atorvastatin calcium. You will receive the study drug on 2 separate occasions at least 14 days apart.

“Investigational formulation” means that the amount of drug and the form that it is in (i.e.: chewable tablet) has not been approved by the United States Food and Drug Administration (FDA).

PURPOSES OF THE STUDY

There are 2 purposes of this study:

1. To see whether atorvastatin in different formulations under study is safe and to evaluate how people feel after taking the study drug
2. To measure the amount of the study drug in your blood after you take a single oral 40 mg dose of commercial Lipitor® and a single oral 40 mg dose of a new investigational formulation of atorvastatin calcium

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The length of time you will be in this study will be about *3 weeks*, not including time between screening and check-in. The time between screening and check-in can be up to 28 days.

This study involves:

2 study periods separated by at least 14 days

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

4 overnight stays

This study does not have follow up visits

Up to 74 healthy male and female subjects, will be in this study.

WHEN ARE YOU ELIGIBLE TO PARTICIPATE IN ANOTHER DRUG STUDY?

The decision for when it is safe for you to participate in another study is determined by the drug safety information gathered from the previous study. For easily eliminated drugs, it may be safe for you to participate in another study as soon as 30 days after the last dose of such a drug. Other drugs may be present in your body longer than 30 days and that may mean you may have to wait as long as six to eight months, or longer, before you can safely enter into another study. These results are usually only known after the last regularly scheduled blood sample taken from you is analyzed to look for leftover drug effects. We will always make this information available to you as soon as we know about the drug level results, and will let you know if there is a longer than usual period of time during which you should not participate in another drug study after this one. Our goal is to keep you from doing anything that may be potentially harmful to you. Your safety while participating in these studies is our primary concern.

It is usually anticipated that the length of time that the study drug used in this study will be present in your body after taking the drug is approximately 4 days.

TO BE IN THE STUDY

To be in this study, you must have an acceptable medical history and acceptable results of your screening test.

You must be between the age of 18 and 55

You must have a Body Mass Index (BMI) between 17.5 and 30.5 and weigh at least 50 kg (110 lbs.)

You must not have had a significant allergic reaction or side effect to any drug, including Lipitor® or other statins

You must not have been in any other drug study for at least 30 days before the first dosing of this study or at any time during the study

You must not have donated a unit of blood (such as at a blood bank) for at least 56 days before the first dosing or at any time during this study

You are advised not to donate any blood for 4 weeks after the study ends

You must not donate plasma or platelets (specific parts of your blood) at any time during the study

You must not have a history of excessive alcohol use

- If you are a female, you must not drink more than 1 alcoholic drink a day (7 alcoholic drinks a week)
- If you are a male, you must not drink more than 2 alcoholic drinks a day (14 alcoholic drinks a week)
- A drink is defined as 12 oz. of beer, 5 oz. of wine, or 1.5 oz. of hard liquor

Study staff may check your breath for the presence of alcohol. If alcohol is detected, you will not be allowed to be in this study

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

You cannot be in this study if you are taking any drugs of abuse. A urine test will be done to check for drugs of abuse

You may not take vitamin, mineral, or nutritional (dietary) supplements for at least 7 days or herbal supplements (including St. John's Wort) or hormone replacement or contraception within 28 days before first day of dosing or at any time during this study

The study doctor must approve any prescription or non-prescription drugs including drugs applied directly to the skin used within 28 days before the start of the study and lasting through the final visit

While on this study please do not eat products that contain poppy seeds, as they may cause a positive drug test

Female subjects must not be pregnant. The safety of atorvastatin investigational formulation during pregnancy has not been determined. This drug could damage an unborn baby if taken during pregnancy. A pregnancy test will be done before the study begins, at check in and at the final visit (the final visit is the last visit in the study for each subject). However, a pregnancy test can be wrong

Female subjects must not be breastfeeding. The study drug may pass into the milk and could be a risk to a breastfed child

During this study it is highly recommended that all male subjects practice abstinence or use condoms as a method of birth control

- All men are required to use medically acceptable birth control measures during participation in this study, as the effects of the study drug on sperm are unknown
- In addition to the condom method, all male subjects without a vasectomy (surgical form of birth control) must advise any female partner to use an additional form of acceptable birth control (as listed later in the document) from the first day of dosing through 28 days after the last dose OR through the completion of follow-up procedures
- Male subjects who have had a vasectomy less than 6 months prior to the first dosing day must also use a condom and advise any female partner to use an additional form of acceptable birth control (see list below) from the first dosing day through 28 days after the last dose OR through the completion of follow-up procedures
- Male subjects with a vasectomy greater than six months prior to the first day of dosing can use a condom only (to prevent transfer of seminal fluid)

You must not smoke or use other forms of tobacco or nicotine products in excess of 5 cigarettes per day

Smoking is not allowed in the Unit

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to:

sign this consent form

give your medical history

- If you are not completely honest with your medical history it may not be safe for you to participate in this study

tell the study staff if you are taking any over-the-counter or prescription drugs or vitamins

As part of the screening process you will be required to complete all of the tests listed below:

Physical examination

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

Vital signs (blood pressure & heart rate), height, and weight

Lab tests (blood and urine)

Urine to test for drugs of abuse (illegal and prescription)

- If this 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 and may be disqualified from the study

ECG (electrocardiogram that records the electrical activity of the heart)

Extra samples of your blood and urine, not needed for this study, may be anonymously tested to measure natural chemicals that are found in the blood and urine. These tests are done to examine the differences among healthy people and to see how much of that difference might be explained by standard factors such as age, sex, height, weight, and race

Blood or urine pregnancy tests for female subjects of childbearing status

During the Study:

During the study you will complete all of the tests listed below:

Prior to being brought to the second floor of the unit for your in-house stay, your belongings will be thoroughly searched. You will be asked to empty your bags and set all of your belongings on the table so the staff can go through them. You will be asked to empty your pockets, remove your shoes and hat, if you are wearing one, and you will be patted down. You may be scanned with a metal detector wand

Updates in medical history

Updates in medications used since screening

Urine drug screen

Pregnancy test

Adverse Event monitoring

Blood samples for PK

Urine samples to test for drugs of abuse may be collected at various times throughout the study

Physical exams will be done at various times throughout the study

Lying blood pressure and heart rate will be measured at various times through out the study

A. Dosing Schedule:

On the dosing day(s) of each study period you will receive your dose on an empty stomach after an 8 hour overnight fast.

We will check your mouth to make sure the study drug has been swallowed

You will receive each of the following dosing treatments on 2 separate dosing days. The dosing days will be at least 14 days apart. The order in which you receive the following doses will be random (like the flip of a coin).

Treatment A; 40 mg commercial atorvastatin calcium (Lipitor®) tablet

This dose must be taken with 8 ounces of water and must be swallowed whole

Treatment B: 40 mg investigational atorvastatin calcium chewable formulation

This dose formulation requires you to chew the tablet and then drink 8 ounces of water

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

Both you and the study staff will know which dosing group you are in.

B. Blood Samples:

During the study blood samples will be taken by individual needle-sticks or by catheter put directly into a vein in your arm. The catheter procedure consists of putting a small tube in your arm to take blood when required. Catheters are used at the judgment of the study doctor or when required by the study plan, not at the request of the subject.

There will be about 31 blood draws. The total volume of blood drawn during the study will be about 97 mL (which is equal to about 4 ounces or 1/2 cup). For comparison, the standard blood donation is about 16 ounces (two cups), once in any 56-day period.

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

The blood samples collected may be used in the future for this study in order to develop tests that will help determine the levels of drug, drug byproducts, or their effects in the body, as well as for your safety should you have a reaction to the study drug.

YOUR RESPONSIBILITIES

Activity Restrictions

You will be confined to the CRU from admission to Day 5 in each period. If prolonged drug effect is noted and your safety is a concern, you may need to remain in the CRU longer. The study doctor or study staff will decide when it is safe for you to leave.

You must not increase your level of physical activity from 48 hours prior to screening, check-in, and/or follow-up visits through the end of the study.

You must call the 24-hour CRU phone number (555) 555-5555 for approval before taking any drugs other than the study drug(s). You must report all such drugs taken during the study to the study staff.

Smoking is not allowed inside the CRU building.

Diet Restrictions:

You must not eat or drink anything for at least 8 hours overnight before each dosing day and 4 hours after each dose.

You must not eat or drink anything for at least 4 hours before each clinical laboratory test. Except for 1 hour before and 1 hour after each dose you may drink water during the periods when you are not eating food.

You must not eat or drink products containing alcohol 24 hours prior to dosing through the end of the study.

You must not eat or drink products containing caffeine from 24 hours prior to dosing through the end of the study.

o Food and beverages that contain caffeine include, but are not limited to, chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®.

You must not eat or drink products containing grapefruit or grapefruit juice from 7 days prior to dosing through the end of the study.

You must be willing to eat all of the food offered during the study.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

You will be required to eat all of the food served to you on Day 1 (dosing day) of each period
Breakfast will be provided on days that you are not dosed except the mornings of check-out
Lunch will be served about 4 hours after dosing
Dinner will be served about 9 hours after dosing
An optional evening snack will be served at about 10 PM on the evenings in-house
With meals and evening snacks you may have drinks that do not contain caffeine (except grapefruit juice)

POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY DRUG(S)

This is the first time the investigational formulation of this drug has been given to people. Therefore, all of the side effects are not known. There may be rare and unknown side effects, including reactions that may be life threatening.

Side effects reported by $\geq 2\%$ of people taking single or multiple doses of atorvastatin (Lipitor®) in clinical trials include the following:

- Abdominal pain
- Accidental injury
- Allergic reaction
- Back pain
- Constipation
- Diarrhea
- Flatulence (gas)
- Flu like symptoms
- Headache
- Infection
- Joint pain
- Muscle pain
- Sinus infection
- Skin rash
- Sore throat
- Stomach upset
- Weakness

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain them to you.

Any subject who experiences a significant side effect during the study may have the following additional procedures done:

- A heart monitor for a continuous reading of the heart's rhythm and rate may be attached
- Blood pressure will be measured often
- A sensing device that measures the amount of oxygen in the blood may be clipped to one finger
- Intravenous (IV) fluids may be given through a catheter inserted in a vein in your arm
- Blood sample collection to investigate the side effect further

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

If you are not honest about your side effects, it may not be safe for you to stay in the study.

ADDITIONAL RISKS OR DISCOMFORTS

Blood Samples:

Possible side effects of having your blood drawn include feeling faint, redness of the vein, and/or pain, bruising, or bleeding at the site of the needle puncture. There is also a slight chance of infection. If you feel faint, notify one of the study staff immediately.

Electrocardiogram:

Possible side effects from having an electrocardiogram include irritation or rash from the adhesive on the patches. If the staff needs to shave the area where the patches need to be, irritation from shaving could occur.

DANGERS OF PREGNANCY AND BIRTH CONTROL

It is very important that women do not become pregnant and men do not make women pregnant during this study. The only certain way to prevent pregnancy is to not have sex. If you are a woman and choose to have sex during this study, you must use a medically proven, acceptable type of birth control. If you are a man and choose to have sex with a fertile woman, you and your partner must use a medically proven type of birth control throughout the study.

If you become pregnant during the study, you will be discontinued from study participation for safety reasons. If you become pregnant within 28 days after you have stopped taking study drug, we ask that you contact the study doctor for safety monitoring. In either case, please make your obstetrician aware of your study participation. The study doctor will ask that you, or your obstetrician, provide updates on the progress of your pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

A pregnancy test could be wrong and if you become pregnant during the study, you may be receiving study drug while pregnant. The effects of the study drug on an unborn or breastfed baby are unknown. If you become pregnant during the study, call the study doctor at once.

It is very important that men do not make women pregnant during this study. The only certain way to prevent pregnancy is to not have sex. If you are a man and choose to have sex with a fertile woman, you and your partner must use a medically proven type of birth control from the first day of dosing until 28 days after the last dose of study drug.

If your partner becomes pregnant during the study until 28 days after last dose or is already pregnant at the time of the study start, you should inform us immediately. She will be asked to sign a consent form to allow the study doctor or her obstetrician to collect updates on the progress of the pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

Acceptable methods of birth control for this study include:

For MALES

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

Abstinence

OR

Use of a condom for males who have had a vasectomy more than 6 months from the first day of dosing

OR

Condom PLUS female partner with one of the following methods:

- Tubal ligation (tubes tied)
- Hysterectomy
- Both ovaries removed
- Copper containing intrauterine device (IUD)
- Diaphragm with spermicide
- Spermicidal foam/gel/film/cream/suppository
- Birth control pills
- Injectable progesterone
- Subdermal (under the skin) contraceptive implant

These methods should be used before the first dose of study drug through the completion of the study.

FOR FEMALES

Abstinence

OR

TWO of the following methods:

- Condom
- Tubal ligation (tubes tied)
- Diaphragm
- Males who have had a vasectomy more than 6 months from the first day of dosing
- Spermicidal foam/gel/film/cream/suppository

These methods should be used from 14 days prior to the first dose until 28 days after last dose of study drug.

Even if you use a medically proven birth control method, there is a chance a pregnancy could occur.

If you are pregnant or become pregnant during the study, the study drug may involve risks to the unborn baby, which are currently unforeseeable.

POSSIBLE BENEFITS OF THE STUDY

Since you do not need treatment with the study drug(s), you will get no medical benefit from being in the study. Information from this study may benefit persons with high cholesterol in the future.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

Since this study is for research only, the only other choice would be not to be in the study.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY (CONFIDENTIALITY)

The clinic staff will record:

- Your medical history
- The dose you receive
- The results of exams and tests done during the study

Your name will not appear in the study data. Instead you will be identified by a subject-identification number. The information from the study data may be shared with others.

Your clinic records may include:

- Health information about you
- Documents that directly identify you

People from the groups listed below may need to look at your clinic records to make sure that the study information is correct and that the study was run as it should have been.

These reviews may take place during the study or after the study is over.

Your study information may be shared with the following people or groups:

- Pfizer Inc or its representatives, including auditors from Groton/New London or other sites and companies Pfizer hires to provide study-related services
- IntegReview, the IRB that approved this study and any other committees responsible for overseeing the research
- Researchers who are conducting this study at other study centers
- Government health agencies (such as the Food and Drug Administration) in the US or other countries
- Accrediting agencies

People from these groups may get information from your study data or may review your clinic records. Because of the need to share information with these people, it may not be possible to keep your identity a secret.

Pfizer will use and share your information only for research or legal reasons or to write research reports. In addition, Pfizer may:

- look at the study data at a later date
- add your information to information from other studies for other research reasons

However, your name will never appear in any reports, or in any future communication by Pfizer.

By signing this consent form, you agree to allow use of your study information even after you leave the study.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

PAYMENT FOR INJURY RELATED TO THE STUDY

If you experience a research injury, the clinic 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 your taking part in the study. Payment for such things as lost wages, expenses other than medical care, or pain and suffering is not offered. To help avoid injury it is very important to follow all study directions. Further information regarding medical treatment for research injuries can be obtained from the study doctor or study staff.

Remember that you must immediately call the study doctor if you have experienced a research injury. A 24-hour answering service is available. Dial the 24-hour clinic telephone number: (203) 401-0300.

You will receive a card with information about this study. This information includes the name or number of the study drug, the clinic 24-hour phone number and the last day of the study. You should keep this card available on your person in case you are involved in a medical emergency.

LEGAL RIGHTS

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

WHOM TO CONTACT

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

Jane Doe, MD
Call the 24- hour Clinic Telephone Number
555-555-5555

If you are unable to reach anyone at the number listed above, and you need medical attention please go to the nearest emergency room.

If you do not want to talk to the study doctor or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject as provided in the Subject's Bill of Rights found in this informed consent form you may contact:

Chairperson
IntegReview
Address
555-555-5555 between 8 a.m. and 5 p.m.

Central Time (call collect)

email@internet.com

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

IntegReview has approved the information provided in this informed consent form and has given approval for the study doctor to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide whether or not you want to be in the study.

PAYMENT FOR BEING IN THE STUDY

The amount of payment is based on a number of factors including the length of the study.

You will be paid \$200.00 for travel expenses to and from screening. You will receive this check within 2 weeks of screening. If you test positive for drugs of abuse on studies that state no smokers are allowed, or if you leave the screening early, you will not be paid the \$200.00.

Further, if you test positive for drugs of abuse:

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

Travel pay for this study has been included in the subject payment
Additional travel pay is not available for this study

The payment for completing the entire study will be up to \$X. If you do not follow instructions, if you are late for blood draws, or if you miss tests, your payment for being in the study will be less. A check will be mailed to you about 2 weeks after you finish the study.

If we ask you to return for additional tests, you will be paid \$X for each trip to the clinic. During times that you are confined to the clinic you will not be paid more for repeat or added tests.

If you discontinue the study, or if you are taken out of the study early, you will be paid for the time you completed. You will not be given the study completion bonus if you drop out of the study early.

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

Study subjects

The total amount you will be paid for this study will be up to \$X if you successfully complete the study

You will be paid \$X for your participation in this study plus a \$X completion bonus if you successfully complete the entire study

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

If you do not follow instructions, if you are late for blood draws, or if you miss procedures, your payment for participation in the study will be reduced

If you choose to leave or are withdrawn from the study before finishing all visits, your payment will be based on how much of the study you completed

- This pay will be based on \$X for each overnight stay (8). A check will be mailed to you about 2 weeks after you finish the study

Back-up Subjects

If you are a back-up subject who is required to stay in the CRU overnight, you will be paid \$X per night that you stay

If you are not required to stay overnight, you will be paid \$X

You will be paid a pro-rated 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 doctor

the study is stopped early

you are qualified but not chosen to participate

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

YOUR DECISION TO BE IN THE STUDY

Whether you are in this study is entirely up to you. You cannot be forced to be in this study. You may not want 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 doctor, Pfizer Inc, IntegReview, or the FDA may take you out of the study without your permission at any time for the following reasons:

If you do not follow the instructions of the study doctor

If we find out you should not be in the study

If the study is stopped

If the study becomes harmful to your health

If you do not follow the 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 clinic for a final visit. This is to make sure that you are in good health.

NEW FINDINGS

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

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

SUBJECT'S BILL OF RIGHTS

As a subject in a research study, you should expect to:

1. Be told of the nature and purpose of the study.
2. Be told about the procedures used in the study and any drug or device to be used.
3. Be told about any side effects, discomforts, or risks that we expect from being in this study.
4. Be told about any benefits you can expect from this study.
5. Be told about any other procedures, drugs, or devices that might be helpful to you, and their relative risks and benefits.
6. Be told about any medical treatment available to you after the study if problems occur.
7. Be given a chance to ask any questions about the study or the procedures.
8. Be told that your consent to be in the study can be withdrawn at any time. You may leave the study at any time without being penalized.
9. Be given a copy of a signed and dated written consent form when one is needed.
10. Be given the opportunity to decide to be in the study without force, fraud, or pressure.

THE REASON FOR INDEPENDENT REVIEW BOARDS AND INFORMED CONSENT

What is a consent form?

The informed consent document contains information required by federal regulations. The informed consent document must be reviewed and approved by an Independent Review Board (IRB). You can tell the IRB has approved this study by dated information at the top of each page.

What is an Independent Review Board (IRB)?

An Independent Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

IntegReview, the IRB for this study

IntegReview is an independent IRB whose board members provide services across the nation.

To meet the requirements of the federal regulations, the IntegReview Board currently includes:

- doctors
- pharmacists
- nurses
- a toxicologist (someone who studies the harmful effects of chemicals)
- a psychiatrist

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

other specialists
others who do not have a background in science or medicine

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\\ntserver\group\sample ic\7-16-08mrkd

AGREEMENT TO BE IN THE STUDY

Subject Number (PIMS#) _____

This consent form 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 form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

Circle one

A. Is this consent form written in a language you understand?

Y

N

B. Do you understand the information in this consent form?

Y

N

C. Have you been given enough time to ask questions and talk about the study?

Y

N

D. Have all your questions been answered completely?

Y

N

E. Do you think you received enough information about the study?

Y

N

F. Do you agree that you were **not** pressured by the study doctor or the study staff to be in this study?

Y N

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care?

Y N

H. Do you know that your health records from this study may be reviewed by Pfizer Inc and by government officials?

Y N

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd

I. Do you know that you can't be in another study while you are in this study?
Y N

**IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN THIS CONSENT FORM.**

You will get a copy of this signed Informed Consent Document for your records.
You agree to participate in this study.
It is your responsibility to tell the study doctor about all changes in your physical or
mental health during the study.

Printed Name of Adult Study Subject

Signature of Adult Study Subject Date
Do Not Sign After *****

Printed Name of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent Date

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Initials/master or site: date

pls\ntserver\group\sample ic\7-16-08mrkd