APPROVED BY
INTEGREVIEW IRB
JANUARY 15, 2019

INFORMED CONSENT
AGREEMENT TO BE IN A GENERAL SCREENING EVALUATION

NAME OF COMPANY: Pfizer Inc

TELEPHONE NUMBER 24 HOURS: (203) 401-0300

INTRODUCTION

You are here today as a possible volunteer for this general screening evaluation. Screening evaluation will be referred to as "screening" in the rest of this document. If you want to be in research studies, this screening will help us know which studies you could be in. Whether or not you take part in this screening is strictly up to you. You may refuse to take part in this screening. The Clinical Research Unit (CRU) staff will be available to answer questions before, during, and after the screening. Today's visit will include some or all of the following to determine your general state of health:

- A medical history
- A physical examination
- Laboratory tests
- Other tests or procedures described later in this document

INFORMATION ABOUT TODAY'S VISIT

- You will not receive any medicine
- The information obtained during this screening visit may be used to fulfill some or all of the requirements of a future research study
- Participation in this general screening does not give consent for your participation in any specific future study
- If you are interested in future studies, you would be provided with detailed information about that study and you would be asked to sign a separate consent document for that study
- This screening does not imply acceptance into any studies conducted by the CRU

Before agreeing to take part in this screening, it is important that you read this form. This form, called a consent form, describes all of the following for this screening:

- Purpose(s)
- Procedures
- Benefits
- Financial payment
- Risks and discomforts
- Your right to withdraw from this screening at any time

If you are not completely honest with your medical history, you may be harmed by being in:

- This screening
- A future clinical research study

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PURPOSE OF THE GENERAL SCREENING

You will not receive any type of drug as part of this general screening visit. Today's screening may show if you are possibly eligible for a future study or studies. Studies that you might wish to consider in the future may include drug studies. If you take part in future research drug studies, you must understand that there is a difference between:

- "Investigational" drugs
- "Marketed" drugs

Marketed drugs:

- Have been approved by the United States (US) Food and Drug Administration (FDA)
- Can be sold in a pharmacy
- May be available over-the-counter or with a doctor's prescription

Usually, there is more information about the use of marketed drugs than investigational drugs.

Investigational drugs:

- Have not been approved by the FDA for a specific use
- May have been given to a few healthy subjects and/or patients with the disease for which the drug is being developed
- Cannot be sold in pharmacies or prescribed by doctors until they receive final approval from the FDA

In some cases, you may be the first or one of the first people to receive an investigational drug. You will be told what type of drug you will be taking if you choose to take part in a research study. However, these drugs are always given:

- According to accepted guidelines
- After appropriate testing in animals

All the effects of investigational drugs in people are not known. There is a chance that new side effects may be found.

SCREENING PROCEDURES

By signing this consent document you are giving the clinic medical provider permission to do general screening procedures. These may include:

- Medical history
- Medication history
- Physical examination (including height, weight, blood pressure, and pulse rate measurements)
- Psychological testing
- History of drug, alcohol, and tobacco use
- Providing your age, gender, race, and ethnicity
- Blood and urine tests (may include some or all of the following):
    - You may need to fast before your visit. If required, the duration of fasting will be between 4 and 10 hours. This will be determined by the investigator and you will be instructed accordingly

  - Screen for drugs of abuse (illegal and prescription) and cotinine (by-product of nicotine)
    - 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 screening
  - Pregnancy testing or blood hormone tests to determine if you are able to have children (women only)
  - Glucose testing (blood sugar)
  - Cholesterol and triglyceride testing
  - Human Immunodeficiency Virus (HIV) testing
  - Hepatitis testing
    - Hepatitis B surface antigen (HepBsAg)
    - Hepatitis B core antibody (HepBcAb)
    - Hepatitis C antibody (HCVAb)
    - Hepatitis B surface antibody (HepBsAb)
  - Standard blood and urine tests to confirm your health status
- Body temperature
- Electrocardiogram (ECG) (to measure the electrical activity of your heart)
- Chest X-rays, lung function testing (blow into a tube to see how well your lungs work), or other non-invasive radiographic (X-ray) procedures
- Ultrasound of the liver (uses sound waves to make pictures of the inside of your body)

Blood samples will be taken by individual needlesticks or finger sticks.

If an unknown medical problem is found during your visit:

- The screening staff will notify you of the problem
- You may be advised to follow-up with your primary care doctor or you may be referred to a specialist for further evaluation
- The clinic medical provider will not pay for this follow-up or referral

During this screening, the total amount of blood drawn will not be more than 50 mL. This is equal to about 1.6 ounces. For comparison, the standard blood donation is equal to about 16 ounces (2 cups).

HIV and Hepatitis Testing:

As part of the screening procedures, and if anyone is exposed to your blood, you will have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS). If you have a positive HIV or hepatitis test, you may not be able to be in other screenings or studies.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling.

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

Positive results for HIV or hepatitis tests or for other infections, or possibly having certain infections, may have to be reported to the State Department of Health. If you have any questions about what information is required to be reported please ask the clinic medical provider or clinic staff.

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

HOW LONG THE SCREENING WILL LAST

This screening will consist of a single visit. This visit will last 1 hour or about 2-4 hours, depending on the procedures that are done. A separate visit may be scheduled if additional procedures are needed such as:

- Chest X-rays
- Lung function testing
- Other non-invasive radiographic (X-ray) procedures
- Ultrasound procedure

TO BE IN THIS SCREENING

To be in this screening you must:

- Not have a recent history of drug or alcohol abuse or addiction
- Not be taking any drugs of abuse
  - A urine drug test will be performed to confirm that you are not using drugs of abuse
  - A test to confirm the presence of alcohol may be completed
- Not be pregnant or lactating (breastfeeding) if you are a woman
  - A pregnancy test will be done if you are a woman able to have children
- Be willing to keep the clinic medical provider informed of any change in your address or telephone number

POSSIBLE SIDE EFFECTS AND RISKS OF THE SCREENING PROCEDURES

Blood Samples:

Possible side effects of having your blood drawn include:

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

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

Finger Stick:

Possible side effects of having your blood taken by a finger stick include:

- Pain at the site of the needle puncture
- Slight chance of infection

ECG:

Possible side effects from having an ECG include:

- Irritation or rash from the adhesive on the patches

A rash may cause 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 happen.

Chest X-ray:

There is always a chance of excessive exposure of radiation with X-rays; however, the effective radiation dose from this procedure is about the same as the average person receives from background radiation in 10 days.

Liver Ultrasound Procedure:

Possible side effects from having an ultrasound include:

A technician will move a wand over your liver. The wand may have a small amount of cool gel on the end to make it move more easily.

A liver ultrasound generally has no risks. You may feel slight discomfort during the procedure if you have existing pain in your liver.

If you do not understand what any of these side effects mean please ask the clinic medical provider or clinic staff to explain them to you.

If you are not honest with the clinic medical provider and clinic staff about any side effects, you may be harmed by staying in the screening.

POSSIBLE BENEFITS OF THIS SCREENING

You may receive the benefit of information about your health. You may also have a chance to be in a future research study that may help others.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY

The clinic staff will record:

- Your medical history
- The results of exams and tests done during the screening

Your name will not appear in the data. Instead you will be identified by a subject-identification number. The information from the 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 screening information is correct and that the screening was run as it should have been.

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

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

- Pfizer Inc or its representatives, including auditors and companies it hires to provide study-related services
- IntegReview IRB, the institutional review board (IRB) that approved this screening and any other committees responsible for overseeing the screening
- Government health agencies (such as the FDA) in the US or other countries
- Accrediting agencies

People from these groups may get information from your 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 data at a later date
- Add your information to information from other screenings or 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 screening information even after you have completed screening.

Please note the following information regarding the delivery of push notifications and text messages:

- The sponsor, or a company working for the sponsor, occasionally may send push notifications and text messages using an automated system to remind you of upcoming appointments, medication reminders and missed doses, or other study-related information
- To discontinue receiving text messages, please contact the Pfizer New Haven CRU at 800-254-6398
- Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier, so please contact your wireless phone provider to inquire 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 research study
- The push notifications or text messages received through this program may appear on your mobile phone screen as soon as they are received, 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

PAYMENT FOR INJURY RELATED TO THIS SCREENING

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 being

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in this screening. 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 screening directions. You can get more information about medical treatment for research injuries from the clinic medical provider or clinic staff.

Remember that you must call the CRU at the telephone number listed on the first page of this consent form immediately if you experience a research injury. A 24-hour answering service is available.

If you are treated for a research injury paid for by Pfizer, Pfizer or its representative will collect your Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the screening you are in to the Centers for Medicare & Medicaid Services (CMS), in accordance 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 this consent form.

WHOM TO CONTACT

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

New Haven CRU
Call the 24-hour clinic telephone number
(203) 401-0300

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 clinic medical provider or clinic staff, if you have concerns or complaints about the screening, or to ask questions about your rights as a screening subject you may contact IntegReview.

IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

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512-326-3001 or
toll-free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information provided in this consent form and has given approval for the clinic medical provider to do this screening. This does not mean IntegReview has approved your personal participation in this screening. You must consider the information in this consent form for yourself and decide whether or not you want to be in the screening.

PAYMENT FOR BEING IN THIS SCREENING

Valid proof of a Social Security Number is required before any payment is released.

If total payment by Pfizer is $600.00 or more in a calendar year, your payment will be reported to the Internal Revenue Service in accordance with Federal tax law.

You will be paid $175.00 for travel expenses to and from this screening. Study payments will be paid in US 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.

You will receive this payment within 2 weeks of the screening. If you test positive for drugs of abuse, , or if you leave the screening early you will not be paid the $175.00.

Further, if you test positive for drugs of abuse:

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

YOUR DECISION TO BE IN THIS SCREENING

Whether you take part in this screening is entirely up to you. You cannot be forced to be in this screening. You may not want to be in this screening. You may leave the screening at any time without penalty or loss of any benefits. Your future medical care will not be affected. The clinic medical provider, Pfizer Inc, or IntegReview IRB, may take you out of the screening without your permission at any time for the following reasons:

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

If you leave the screening or if you are taken out of the screening for any reason, you may be asked to return to the clinic for a final visit to have some additional follow up or tests. This is to ensure your safe exit from the screening. In addition the data collected to the point of your withdrawal remains part of the clinic database and may not be removed. You can ask that any unused samples that were collected be destroyed by contacting the clinic medical provider.

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THE REASON FOR INSTITUTIONAL 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 IRB. You can tell the IRB has approved this screening by dated information at the top of each page.

What is an Institutional Review Board (IRB)?
An 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 screening
IntegReview is an IRB whose board members provide services in the US, Japan, and Latin America.

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

- Doctors
- Pharmacists
- Nurses
- Toxicologists (people who study the harmful effects of chemicals)
- Other specialists
- Others who do not have a background in science or medicine

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AGREEMENT TO BE IN THIS GENERAL SCREENING: PIMS#: _____

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

By checking each of the following, you are agreeing that the statements below are true:

		Please Check
A.	This consent form is written in a language I understand.	
B.	I understand the information in this consent form.	
C.	I have been given enough time to ask questions and talk about the screening.	
D.	All of my questions have been answered completely.	
E.	I think I have received enough information about the screening.	
F.	I agree that I was not pressured by the clinic medical provider or the clinic staff to be in this screening.	
G.	I know that I can leave the screening at any time without giving a reason and without affecting my healthcare.	
H.	I know that my health records from this screening may be reviewed by Pfizer Inc and by government officials.	
I.	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 THIS CONSENT FORM.

- You will get a copy of this signed and dated Informed Consent Document for your records
- You agree to participate in this screening
- It is your responsibility to tell the clinic medical provider about all changes in your physical or mental health during the screening

_____
Printed Name of Adult Screening Subject

_____
Signature of Adult Screening Subject Date

_____
Printed Name or Initials of Person Explaining Informed Consent

_____
Signature or ALPHA NUMERIC CODE of Person Explaining Informed Consent Date

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