

TEMPLATE

*Every attempt should be made to use an understandable reading level in all consent documents.
Subject should initial each page of the informed consent as it is explained to them.*

SUBJECT INFORMATION AND CONSENT FORM

Name of Research Study: _____

Protocol #: _____

Sponsor: _____

Principal Investigator Name: _____

Research Site Address(es): _____

Daytime telephone number(s) _____

24-hour contact number(s) _____

Purpose of the Subject Information and Consent Form

This Subject Information and Consent Form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your study doctor will be paid by the sponsor to conduct this research study.

OPTIONAL-This Subject Information and Consent Form has been developed for use in a research study that may involve some subjects who do not have the legal capacity to consent to their participation. Accordingly, when the subject cannot legally consent to take part, the pronouns "you" and "your" should be read as referring to the subject rather than the legally authorized representative who is signing the form to give consent for the subject to take part in the research study.

Purpose and Description of the Research Study

You are being asked to take part in a research study of an experimental _____.
“Experimental” means that the study drug is currently being tested and is not approved for sale in the United States by the Food and Drug Administration (FDA).

The purpose of this research study is to _____

This study will involve about ____ subjects at about ____ different centers in the United States.

The study will take place over (*time in weeks, months or years*) and will include about (*number*) office -visits to the study doctor.

Study Procedures

If you agree to take part in this study, you will first sign this Subject Information and Consent Form before any study-related procedures are performed. You will _____ (*describe study procedures and specify if anything is considered experimental, when applicable, include the total amount of blood that will be drawn during the study, when applicable*). Also include the probability of random assignment to each study treatment.

Upon study completion or early withdrawal, it is important for you to speak with your study doctor to arrange follow-up care.

Subject’s Responsibilities

While participating in this research study, you will need to:

- *State subjects’ responsibilities in bullet format*
-

Risks or Discomforts

Your condition may not improve and could even worsen if you take part in this study.

The currently known risks include :(*Add risks here, including risks of placebo and any information regarding the quantity (i.e. frequently, rarely) or duration of risks,(e.g., “will go away when stopped”)*)

Risks associated with drawing blood from your arm include pain, bruising, lightheadedness and, on rare occasions, infection.

When taking any new medication, you should exercise caution and not drive, operate machinery, or engage in other activities requiring mental alertness until you know how the medication will affect you.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known. Also the risks or discomforts described may occur more often or be more severe than has been seen before.

Subject’s Initials_____

If participants may become pregnant or father a child, and the risks to the fetus are unknown, add the following:

The effects of (name the drug, device, biologic or procedure) on a fetus are unknown. If you become pregnant or father a child while on this research study, an injury to the fetus may occur that has not been seen before or is worse than seen before.

The study drug must be taken only by the person for whom it has been prescribed. It also must be kept out of the reach of children or persons of limited capacity to read or understand.

New Findings

Your study doctor will tell you of any information learned during the course of the study that might cause you to change your mind about taking part in the study. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

Possible Benefits

Your symptoms of _____ (*enter disease or condition*) may improve while participating in this study. Your participation in the study will contribute to information about the study drug and may benefit other patients in the future.

Payment to Subject for Participation

For your participation, you will be paid \$_____ for each completed visit for a possible total of up to \$_____.

OR

You will not receive any payment for taking part in this research study.

Costs

You do not have to pay for study drug, study visits, and tests that have to be done for the study.

OR

State what the costs of participation will include, particularly time and travel and costs of any or background therapies.

Alternative Treatments

You do not have to take part in this study to receive treatment for your condition. If you decide not to take part in this study, there are other treatments for (*state condition and give examples*).

Your doctor will discuss alternative treatments with you. *State the important appropriate, alternative procedures or courses of treatment that may be advantageous to the subject and their important potential benefits and risks.*

Confidentiality and Release of Medical Records

We will protect information about you and your taking part in this research study to the best of our ability. If information about this study is published, your identity will remain confidential.

Subject's Initials_____

However, the U.S. Food and Drug Administration (FDA), Copernicus Group Independent Review Board (IRB), and (*list other sponsors/CROs*) may sometimes inspect the medical records and study information of those who take part in this study. By signing this consent form, you are authorizing such access. A court of law could order medical records shown to other people, but that is unlikely. Therefore, absolute confidentiality cannot be guaranteed.

Compensation for Research Related Injury

If you are injured as a result of the study drug or study procedures performed during your participation in this research study you should seek medical attention at the medical provider of your choice. The Sponsor will cover the medical expenses necessary to treat the injury only to the extent that such costs are not covered by your health insurance policy, by a government program, or by any other third party.

You must follow the directions of the study doctor to be eligible for this coverage.

Neither the Sponsor nor the study doctor has a program in place to provide other compensation in the event of an injury.

Legal Rights

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this Subject Information and Consent Form.

Voluntary Participation

Your decision to take part in this research study is completely voluntary. There will not be any penalty or loss of benefits to you if you decide not to take part.

In addition, you may withdraw from the study at any time. There will be no penalty if you decide to withdraw from the research study. Before withdrawing from this study, notify your study doctor that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal. You may be asked to return to the clinic for tests.

Withdrawal

Your doctor, the sponsor company, or the FDA has the right to stop your participation in the study at any time, with or without your consent, for any of the following reasons: if you have an adverse effect from the study drugs, if you need a treatment not allowed in this study, if you do not keep appointments, if you do not take the study drug as instructed, if you become pregnant, or if the study is canceled by the FDA or the sponsor company. The sponsor may decide to stop the study and your access to the study under certain circumstances even if the study drug appears to be safe and effective.

You may withdraw from the research study at any time. Your decision will not affect any benefits to which you are entitled.

If you decide to withdraw before the end of the study, there may be risks associated with this decision. You should discuss potential risks of withdrawal with your study doctor (*state what*

Subject's Initials_____

these potential risk may be). For your safety, the following procedures may be requested if you leave the study early:_____.

Contact for Questions

If you have any questions about your participation in this research study, or if you feel that you have experienced a research-related injury or reaction to the study drug, contact:

Investigator Name: _____

Daytime telephone number(s): _____

24-hour contact number(s): _____

If you have questions about your rights as a research subject, you may contact Copernicus Group Independent Review Board (IRB) at 1-888-303-2224 (toll free). An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind. **Copernicus Group IRB has reviewed and approved the research study described in this Subject Information and Consent Form.** If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at www.cgirb.com.

Subject's Initials_____

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Signature of Subject

Date

Subject's Initials_____

Subject’s Statement of Consent

- I have been told that this is a research study of an experimental _____.
- I have been given sufficient opportunity to consider whether to participate in this study.
- My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty or loss of benefits or treatment to which I am entitled.
- If I meet the criteria and would like to take part in this research study, my doctor may enroll me in the research study.
- The research study may be stopped at any time without my consent either by the study doctor or by the company sponsoring the research.
- I have been told that my study doctor will be receiving payment from the sponsor to conduct the research.
- I have had an opportunity to ask my study doctor questions about this research study. My questions so far have been answered to my satisfaction.
- I have been told how long I may be in the research study.
- I have been told of the procedures and tests that may be performed during the research study.
- I have been told what the possible risks and benefits are from taking part in this research study. I may not benefit or my condition may worsen if I take part in this research study.
- I do not give up my legal rights by signing this form.
- I have been told that prior to any study related procedures being performed, I will be asked to voluntarily sign this subject information and consent form.
- I authorize access to my medical records by the sponsor, CRO, Copernicus Group IRB, or applicable regulatory agency.
- I have been told that I will receive a signed and dated copy of this subject information and consent form.

I voluntarily agree to take part in this research study.

Signature of Subject or Legally Authorized Representative (LAR) Date

Printed Name of Subject

I certify that the information provided was given in language that was understandable to the subject and/or LAR.

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

Subject’s Initials_____

**AUTHORIZATION TO USE AND DISCLOSE PERSONAL
HEALTH INFORMATION FOR RESEARCH**



Name of Research Study: _____

Protocol #: _____

Sponsor: _____

Principal Investigator Name: _____

Research Site Address(es): _____

Daytime telephone number(s) _____

24-hour contact number(s) _____

Pager number(s) _____

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

In working with the sponsor, the study doctor, _____, will use and share personal health information about you. This is information about your health that also includes your name, address, telephone number or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives may review or copy your personal health information at the study site. Regulatory authorities and the Copernicus Group Independent Review Board may also review or copy your information to make sure that the study is done properly or for other purposes required by law.

Subject's Initials _____

By signing this Authorization, you allow the study doctor to use your personal health information to carry out and evaluate this study. You also allow the study doctor to share your personal health information with:

- the sponsor and its representatives
- the Copernicus Group Independent Review Board
- the U.S. Food and Drug Administration (FDA)
- other regulatory agencies

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this Authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to [study doctor's name & address].

If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

Subject's Initials_____

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, the Copernicus Group Independent Review Board, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

Printed Name of Subject

Signature of Subject

Date

Printed Name of Person Obtaining Authorization

Signature of Person Obtaining Authorization

Date

OPTIONAL

I certify that under state law I am the legally authorized representative of the Subject named above. I am the responsible person legally permitted to sign this Authorization to release the Subject's medical records and health information as described above.

Printed Name of Legal Representative

Signature of Legal Representative
(Relationship to the Subject)

Date

Subject's Initials_____