Subject Information and Informed Consent

Name of Research Study:

Protocol Number:

Sponsor:

Principal Investigator Name:

Research Site Address: (may include phone number)

This form may have 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.

Introduction
You are being asked to take part in a research study. Before you agree to take part in this study, please read this consent form and ask as many questions as you need to be sure you understand the possible risks and benefits.

This consent form has important facts to help you decide if it is in your best interest for you to take part in this study. If you have questions that are not answered in this consent form, one of the research staff will be able to give you more information.

Purpose of the Study
The purpose of this research study is …

Description of the Research Study
This study will involve about ____subjects at ___ different locations in the United States.
You will be asked to be in this study for about _____.
(Include what will take place at each visit.)

Risks or Discomforts
- The risks of being in this study have been found ….
-

Along with the discomforts listed here, there may be others that we may not yet know about. These risks may or may not be related to the use of this …...

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New Findings
Your doctor will tell you of any information learned during this study that might cause you to change your mind about taking part in this study.

Possible Benefits
There may be no direct benefit from being in this study. However, use of the …..

Alternative Treatments
If you decide not to take part in this study, there are other … Your doctor will tell you about these procedures.

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 printed for the public, your name will not be given out. However, the U.S. Food and Drug Administration (FDA), the institutional review board, the _____ Hospital, the sponsor (including monitors and auditors), or the _____ may sometimes look at the medical records and study information of those who take part in this study. Therefore, **total privacy cannot be guaranteed**.

Compensation for Research Related Injury
Reactions or complications, both ones that we know about, and those we do not know about are possible in any research study. This can happen without any fault to you, your doctor, your hospital, and study sponsor. If you are hurt by the study drug or properly performed study procedures, and you have followed the directions of the study doctor or other study staff, the Sponsor will cover the medical costs needed to treat the injury. You will be given the medical care needed to treat this injury. No other payment such as money for lost wages will be given to you by the sponsor or ____.

Legal Rights
The above section does not stop you from seeking legal aid.

Contact for Questions
If you have any questions, concerns, or complaints about being in this study, or if you feel that you have had a research-related injury or problem with the study drug, contact *(investigator name, daytime phone number and 24-hour number).*

If you have questions, concerns, or complaints that are not answered by the research team, or you want to talk to someone other than the research team about your rights as a research subject, you may contact Liberty IRB at (386) 740-9278. Liberty IRB (an institutional review board) reviewed this study and is a group of people who review research studies to protect the rights and welfare of research participants. Review and approval by Liberty IRB does not mean that the study is without risks.

Voluntary Participation
If you decide to take part in this study it is completely of your own free will. There will not be any penalty or loss of benefits to you if you decide not to take part.

Also, you may withdraw from the study at any time. If you decide to withdraw from the research study, there will be no penalty or loss of benefits to you. Before stopping this study, you must contact your study doctor. This notice will allow your doctor to tell you about any possible medical risks of stopping the study. You may also be asked to return to the doctor's office for tests.

Withdrawal
Your doctor, the sponsor company, or the FDA can stop the study at any time with or without your consent for any of the these reasons: if you have an adverse effect from the study medicines, if you need a treatment not allowed in this study, if you do not keep doctor visits, if you do not take the medicine as you are told, if you become pregnant, or if the study is cancelled by the FDA or the sponsor company.

Cost
Costs associated with the use of the _____ will be billed to you or your insurance company in the usual manner. No additional costs are associated with participation in this study.

Compensation for Participation
(If compensation is provided explain here.)

Authorization To Use And Disclose Protected Health Information

While you are participating in this research study, the study doctor and his staff will collect and create personal health information about you and record it on forms. This information may include health histories, examinations and results of tests. The study doctor will keep this information in study records. He may also gather information regarding your past, present, and/or future medical conditions from your primary medical doctor. These records may also include personal information such as your birth date, social security number, or medical record numbers which could be used to identify you. This type of information is called "Protected Health Information" (PHI).

Under a federal law called the "Privacy Rule," your PHI that is gathered and obtained during research cannot be used to conduct the research or be given to anyone for research purposes without your permission. Because of this rule, you may not participate in this study unless you give your permission to use and disclose your PHI.

By signing this authorization (agreement), you are giving permission for the study doctor and his staff to use your PHI to conduct this study, to monitor your health status, and possibly to develop new tests, procedures and commercial products. You are also agreeing to allow your PHI to be disclosed to the study sponsor and any representatives

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working with them. The sponsor may also give your PHI to the Food and Drug Administration or other regulatory agencies. Normally, the study staff will assign a code number to you for this study. This will help to protect your identity; however, the sponsor may look at your complete study records which will identify you. The sponsor will also send representatives to your doctor's office to oversee how the study is being conducted. These representatives will review your PHI to make sure the information is correct. The Institutional Review Board (IRB) may also have access to your PHI to meet its responsibilities as an IRB. These disclosures help to make sure that all information related to the research is available to those who need it.

Your identity will remain confidential and except for the disclosures described above, will not be shared with others, unless it is required by law. If your PHI is given to the parties listed above or to anyone who is not required to comply with federal law, your PHI will no longer be protected by the "Privacy Rule" and could possibly be used or disclosed in ways other than are listed here.

You have the right to see and make copies of your PHI. You are agreeing, however, not to see or make copies of your PHI until all of the sponsor work has been completed. At that time, you may ask to see your records.

This authorization will never expire. You have the right to cancel or withdraw this authorization at any time. If you cancel this authorization, your PHI will no longer be used for this study, unless it is necessary (based on your earlier authorization) to complete analysis and reports for this research.

To cancel your permission to use your PHI, you must send a written notice to your study doctor's office stating that you are canceling your authorization to use or disclose your Protected Health Information. If you cancel this authorization, you will not be allowed to continue in this study.

Additional Information

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

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Subject Consent

I choose to participate in this study. I have read all of the above or it has been read to me. I have had the chance to ask questions about this study and my questions have been answered. After I sign this consent form, I will be given a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____ _____

Signature of Participant Date

_____ _____

Signature of Person Obtaining Consent Date

_____

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