PRE-SCREENING CONSENT FORM

The following information is provided for your benefit to help you understand what will be occurring at this pre-screening visit. Before agreeing to receive these tests, it is important to read and understand the following explanation of the proposed procedures. This consent form may contain words that you do not understand. You may ask the study doctor or study staff to explain any words or information to you that you do not clearly understand. By signing this form you signify that you fully understand the consent form and volunteer to have these procedures performed.

SITE Volunteer Research Group
1928 Alcoa Highway, Suite 107
Knoxville, Tennessee 37920
(865) 305-9356

PURPOSE
In an effort to determine your health status for possible research studies with us, we are asking that potential volunteers be seen by our research personnel to complete preliminary testing. We will obtain your medical history information, medication history and your vital signs. We may also conduct other tests in order to determine whether you are able to participate in a research study at this clinic. This may included any of the following: electrocardiogram (ECG), which is an electronic tracing of your heart, draw blood samples (could be used to determine sugar levels, cholesterol, kidney and liver function tests, test for illicit drugs or alcohol abuse and other important analysis), treadmill testing (to assess the heart for any blockages and/or arrhythmias), doppler of the legs (an ultrasound to measure pressure in leg arteries), spirometry (to measure lung status/function), heart echocardiogram (ultrasound test to assess the heart size and valves), urine sample (for drug screening and/or routine urinalysis). It is important to have this information to ensure that you are healthy enough to qualify for research studies. The study physician may perform a physical examination at this time also.

RISKS
Drawing blood samples is almost without risk, but may cause some mild discomfort, such as swelling, temporary sensation of pain, or burning and/or a bruise, which may persist for a few days. Less common risks include the following: the formation of a small blood clot at the site of the puncture and/or swelling of the vein and surrounding tissues, and possible bleeding from the puncture site.

ECGs are usually pain free, however, some discomfort may be experienced if areas require shaving or if the adhesive material causes a rash. This usually clears up quickly.

Treadmill tests are also usually performed without complication, however, some people may experience fatigue and occasionally people have fallen getting on or off of the treadmill. The staff will assist you to help prevent these problems. It is important that you listen and comply with the instructions that you are given. Treadmill exercise testing carries a slight risk of causing heart rhythm abnormalities. Should such arrhythmias (irregularity in the force or rhythm of the heartbeat) occur, proper drugs and equipment will be readily available for treatment.

Spirometry testing, which is done to test your lung capacity, may cause you to become light-headed and/or dizzy.

Ultrasound tests use high-frequency sound waves, the same technology used to take pictures of babies before they are born. You should feel no major discomfort during the test. You may feel coolness from the gel used and a slight pressure on your chest.

The blood pressure measuring cuff that goes around your arm and is inflated, may cause some mild discomfort, bruising or red blood spots on the arm to which it is applied. Your blood pressure may be taken as part of a measurement of your vital signs.

UNFORESEEABLE RISKS

Your consent to pre-screening procedures is with the knowledge that there may be harmful physical or mental results that the study doctor has no way of knowing about ahead of time.

BENEFITS

Pre-screening tests and procedures are not designed to benefit your health directly. You may receive important information about your health from the various tests and procedures.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Your personal health information is protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Volunteer Research Group (VRG) will collect and create personal health information about you and record it on forms. This form provides information about how these medical records and health information will be used and disclosed.

Your records may include information about your blood samples, physical examinations, medical history and any other data collected or reviewed. Your records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you.

By signing this form, you also allow VRG to disclose your records to a pharmaceutical company (known as a "sponsor") and their representatives, agents and/or consultants. VRG will use the information to determine if you qualify for a research study. The data sent by the study doctor to a sponsor usually does not include your name, address or social security number. However, the sponsor might review or copy all of your records to assure the quality of the study or for other uses allowed by law.

All of your records, the signed consent form(s) and this pre-screening consent form also might be reviewed and/or copied by the U.S. Food and Drug Administration (FDA), by Crescent City IRB or by other regulatory agencies in this country and other countries. These agencies might review your records to check the information collected in a research study, to check how the study was conducted or for other uses allowed by law.

Federal and state laws require the research doctor to protect the privacy of your records. However, absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. In addition, after the research doctor discloses your records to others, then the law may no longer protect the privacy of the information.

If you would like to know how a sponsor will protect the privacy of your records, ask the study doctor how to obtain this information. If you would like to know how Crescent City IRB will protect the privacy of your records, you can contact the IRB at 1-504-822-4067. You have the right to see and copy your records as long as the doctor has this information in his or her possession.

This authorization does not have an expiration date. If you do not cancel this authorization, then it will remain in effect indefinitely. You can cancel this authorization at any time by giving a written notice to the doctor. If you cancel this authorization, then you no longer will be able to participate in pre-screening. If you cancel this authorization, then the doctor will no longer use or disclose your records.

COMPENSATION
No compensation will be offered to you for having any pre-screening tests and/or procedures done.

WITHDRAWAL
Your participation in this pre-screening is voluntary. You have the right to refuse to participate, or to withdraw from participation, at any time for any reason. The research doctor may end your participation in the pre-screening process, without your consent, for any reason that he/she believes is appropriate.

QUESTIONS
If you have any questions, of if you experience any medical problems, please contact the study staff at Volunteer Research Group at 865-305-9356. If you have any questions in regards to your rights as a research volunteer, you should contact Dr. Brandon Wool, Chairman, Crescent City IRB at 504-822-4067. You may place a collect call if needed.

CONSENT and AUTHORIZATION
I have read all information in this pre-screening document, and all my questions have been answered to my satisfaction. I voluntarily consent to pre-screen for potential research studies with Volunteer Research Group.. I understand that I will be given a signed copy of this consent form, and have been given the name and telephone number of both the research site and the IRB. My signature gives my consent to participate. I authorize the release of my medical records and health information related to this pre-screening, including my signed consent form or any addendum, to a sponsor and its representatives, the FDA, Crescent City IRB and other regulatory agencies as described above. By signing this form I have not given up any of my legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Authorization

_____ _____
Signature of Person Obtaining Authorization Date