IRB Approved for
Non-Protocol
Specific
Aug 08, 2019

Clinical Research of Gastonia

Clinical Research of Gastonia Pre-screening Consent

Participant Name: _____ Date of Birth: _____

Today's Date: _____ Participant's Phone Number: _____

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about this pre-screening as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this pre-screening, you must sign your name at the end of this form and date it.

Clinical Research of Gastonia and any entity owned, controlled or managed by any such entity are "Affiliates of Company and Company"

Clinical Research trials conducted within Clinical Research of Gastonia have criteria that must be met to be included as a study subject. In order to determine the ideal trial, it may be best to perform one or more tests to obtain results to pre-screen you for trials. Various information can be obtained to ensure the best suited study is offered to the individual. Therefore, you should determine below which procedures, tests, and measures you would consider being performed.

Pulmonary Function Test (PFT) is a series of breathing tests also called spirometry or breathing tests. Spirometry measures how quickly and how much air can move in and out of your lungs. While this test usually produces minimal discomfort, certain changes may occur. Ricks associated with pulmonary function testing may include shortness of breath, dizziness, or headache during the breathing tests. Rarely, there is a possibility of passing out (syncope) during the test. We may ask to you take 4 puffs of Albuterol (which is an approved medication often used by asthma and COPD patients) or Atrovent (which is an approved medication often used by COPD patients) to determine how much reversibility (lung function improvement) you obtain. This reversibility test will better assist with trial options.

Glucose is a measure of blood sugar level and can indicate your risk for diabetes. You use a method called fingerstick to obtain blood for glucose analysis. This finger stick test may be a little uncomfortable, when the lancet goes into your finger, but it is very quick and very little blood is drawn, only a drop or two.

Lipid Panel: When cholesterol is measured, you receive several different numbers that give you a total "lipid profile," which is a detailed measure of the fats in your blood. Cholesterol is a soft, waxy fat. It is found in the blood stream and is something your body and cells need. Cholesterol can be dangerous, however, when it sticks to the sides of arteries and forms a buildup that blocks blood flow. This lipid panel result is obtained through fingerstick process as listed above for glucose testing.

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Hemoglobin A1C Level (HbA1c): The A1C test measures your average blood glucose control for the past 2 to 3 months. It is determined by measuring the percentage of glycated hemoglobin, or HbA1c, in the blood. This is obtained through venous blood collection. A small amount of blood will be removed by putting a needle in your vein. This is the standard medical method used to obtain blood for tests. There is momentary pain at the time the needle is inserted into the vein, but other discomfort should be minimal. In about 10% of the cases there is a small amount of bleeding under the skin which will produce a bruise. All methods of infection prevention are used by utilizing new sterilized needles, alcohol wipes to prep the skin and gloves are worn.

Blood Pressure is obtained to determine if your blood pressure is normal, hypertensive (above normal range) or hypotensive (below normal range). As the blood pressure "cuff" or band tightens around the arm, this test may temporarily cause discomfort for a minute. On rare occasions, people are bruised by the test.

Clearance from your treating medical physician may be obtained in order for you to participate in clinical trials. Clearance is obtained to give authorization from your treating physician that your medical conditions are not clinically significant and/or are treated and/or stable prior to your enrollment in a clinical trial.

Mark the box (es) to which you would give permission for collection (mark all that apply):

	Pulmonary Function Test (PFT)
	Lipid Profile
	Glucose Testing
	HbA1c
	Blood Pressure
	Obtain treating physician clearance to participate in clinical trials

Physicians Clinical Research of Gastonia is requesting clearance from:

_____

_____

Any questions you may have about the above listed procedures are encouraged. If you or the person consenting for you has any doubts or questions, please ask for further explanation.

Consent to perform these tests is voluntary, the only alternative is to not participate in this pre-screening. You or the person authorized to consent for you may choose to not participate or you may withdraw from the pre-screening for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor can stop your participation at any time without your consent.

Any new important information that is discovered during the pre-screening and which may influence your willingness to continue participation in the pre-screening will be provided to you.

COSTS

The pre-screening test(s) will be done at no cost to you or your insurance company.

COMPENSATION FOR PARTICIPATION

You will not receive any monetary compensation for your participation in this pre-screening.

CONFIDENTIALITY

Pre-screening records will be kept confidential, except as required by law. The study doctor and study staff will look at your pre-screening records and information to determine your eligibility for possible participation in a research study. In addition, pre-screening records may be provided to study sponsors or regulatory agencies, such as the United States Food and Drug Administration (FDA), if you qualify and participate in a research study.

BENEFITS

This pre-screening is provided for your information only and does not take the place of seeing your primary care physician or specialist. The study doctor requests that you follow-up with a physician if your test results do not fall within the normal range.

I have read the above statement, or it has been read to me. I understand the procedure(s) and the usual risks associated with the procedure(s). I understand that this is only a preliminary test to see if I may qualify for a clinical trial and there will be no direct benefit to me from my participation. This does not constitute a study visit. I understand that I will not pay for the procedure(s) and I will not be compensated for the procedure(s). I have had the opportunity to ask questions about the procedure(s). All of my questions have been answered to my satisfaction. I give permission to have the above procedure(s) performed.

_____ OR _____

Participant's Signature Date Signature of Authorized Person Date

_____

(Authority of Legally Authorized Representative to act on behalf of Subject)

*Authority to act on behalf of another includes, but is not limited to parent, guardian, or durable power of attorney for health care.

_____ AND _____

Witness Signature Date Physician Signature Date