PRESCREENING INFORMED CONSENT

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INTRODUCTION

Before agreeing to participate in this/these prescreening test(s), it is important that you read and understand the following explanation of the proposed prescreening and of the purpose, procedures, benefits, risks, discomforts and precautions of these tests. It also describes the alternative procedures that are available to you and your right to withdraw from the prescreening at any time. No guarantees or assurances can be made as to the results of the prescreening. This consent document may contain words that you do not understand. Please ask the staff to explain any words or information that you do not clearly understand. If the results of these prescreening tests and further assessment show that you may qualify for a research study being conducted at Quality Research Inc. (QRI), either now or in the future and if you wish to participate in it, you will be asked to review, sign and date a separate informed consent document. Your demographic and health information will be entered into the QRI database.

If you are not completely truthful with the QRI staff regarding your health history, you may harm yourself by participating in this prescreening.

PURPOSE

The purpose of this/these prescreening test(s) is to conduct a generic screening to determine if you pre-qualify to participate in a research study being or to be conducted at QRI.

PRE-SCREENING TEST(S)

Before any prescreening tests or procedures are performed, you will be asked to read, sign and date this informed consent document. The following checked procedures may be performed as well as a brief review of your medical history and current medications:

- Vital Signs (Blood Pressure, Pulse Rate, and Body Temperature)
- Height, Weight, Body Measurements, and/or Body Mass Index (BMI)
- Blood Sugar (Will involve a needle stick on the finger)
- Laboratory Tests (Will involve a blood sample)
- Electrocardiogram (ECG or EKG) – This is a non-invasive test to check the electrical activity of your heart by placing electrodes on your chest, arms, and legs which will transfer an image of your heart's activity to paper by the ECG/EKG machine. No electricity passes through your body from the machine.
- Pregnancy test (Urine)

- Urinalysis (Dipstick)
- Urine drug screen
- Dermatological assessment (Skin)
- Ultrasound procedures (Non-invasive testing that uses reflected ultrasound waves to evaluate tissues or blood flow)
- DEXA Scan (Bone density scan)
- X-Ray
- Pulmonary Function Test (Inhaling/exhaling into a device to measure lung function/capacity)
- Other: _____

You will receive a copy of your prescreening test results for your information and QRI study staff or doctor will explain the results to you.

RISKS AND/OR DISCOMFORTS

Blood Pressure: You may experience some discomfort or rarely bruising when the cuff squeezes the upper arm.

Electrocardiogram (ECG/EKG): Patches placed on your upper chest, arms, and legs may cause redness and/or skin irritation.

Blood Sample: Possible risks of giving a blood sample are localized pain, small bruises, faintness, bleeding or infection. Fasting for certain blood tests may cause you to feel sick to your stomach or light-headed.

DEXA Scans: A bone density scan exposes you to a small dose of radiation. During the DEXA scan, you will be exposed to radiation. However, your exposure will be lower than with a chest x-ray. The DEXA scans are considered, in general, less harmful than a standard x-ray.

X-Rays: X-rays involve exposure to radiation. Although all radiation is cumulative over your lifetime, small doses from this procedure should not create a significant risk to your health.

Unknown Risks: All other procedures have no foreseeable risks. However, there may be risks and discomforts that are unforeseen.

BENEFITS

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

NEW FINDINGS

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

COMPENSATION FOR INJURY

If you are injured as a result of procedures performed for the purpose of this prescreening, you will be responsible for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. There are no plans to provide other

compensation beyond that which is listed in this informed consent document. You will not lose any of your legal rights or release the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing and dating the consent document.

COSTS

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

COMPENSATION FOR PARTICIPATION

No compensation is available for your participation in this prescreening test process.

CONFIDENTIALITY

Prescreening records will be kept confidential, except as required by law. QRI study staff will look at your prescreening records and information to determine your eligibility for possible participation in research studies being or to be conducted at QRI.

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in the prescreening tests, QRI study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures undergone), and record it in your records. These will contain medical and other information that could be used to identify you (referred to as "Protected Health Information" or "PHI"). By signing and dating this form, you are agreeing to allow QRI to use you PHI to determine if you may qualify for a research study. You may not participate in this prescreening if you do not sign and date this form.

With your permission, QRI will retain your PHI on file and/or in a database for the purpose of contacting you regarding possible participation in future studies. Your identity will remain confidential.

If you qualify for a research study and agree to participate, your PHI will be placed in your study-related records and used for the purpose of conducting the study. Your PHI may be disclosed to the sponsor or persons working on behalf of the sponsor. In addition, the United States Food and Drug Administration (FDA) or other regulatory agencies, and the institutional review board (IRB), an independent committee that helps protect the rights and welfare of research subjects, will have access to your PHI. Except for these disclosures, your PHI will not be shared with others unless such disclosure is required by law. If you PHI is given to the parties listed above or others, your PHI may no longer be protected by the federal Privacy Rule and could possibly be used or disclosed in ways other than those listed here.

This Authorization does not expire unless you revoke (cancel or withdraw). You have a right to revoke it at any time. If you revoke the Authorization, QRI will no longer use your PHI, except to the extent he/she has already taken action based upon your Authorization. To revoke your Authorization, you must write to QRI and the address listed on the first page of this form and tell a staff member that you are revoking your authorization to use or disclose your protected health information. If you revoke this Authorization, you will not be allowed to continue with the prescreening process.

ALTERNATIVES AND VOLUNTARY PARTICIPATION

Your alternative is not to participate in this prescreening test and to seek diagnosis and treatment from your doctor. Your participation in this prescreening is voluntary. You may decide not to participate, and you are free to stop the test at any time without prejudice to your future participation in medical treatment, health screenings, or in other research studies.

WHOM TO CONTACT ABOUT THIS STUDY

During the prescreening process, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the prescreening, please contact the staff at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this prescreening.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this prescreening, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

CONSENT

I have read and understand the information in this consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in the prescreening test(s) described in this consent document until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated document after I have signed and dated it.

Subject

_____

Printed Name of Prescreen Subject

_____ _____

Signature of Prescreen Subject Date

Staff Conducting Consent

_____

Printed Name of Person Conducting the Consent Discussion

_____ _____

Signature of Person Conducting the Consent Discussion Date