IRB APPROVED
APR 13, 2022

PRE-SCREENING GENERAL CONSENT

SITE(S):

Summit Headlands LLC
2701 NW Vaughn St. Suite 350
Portland, Oregon 97210

STUDY-RELATED PHONE NUMBER(S):

(503) 279-8252

Summit Headlands LLC ("Summit") conducts clinical trials (research studies) using investigational treatments. In order to determine if a potential participant might be eligible for a study, pre-study medical, cognitive or psychiatric evaluations are performed. These evaluations are for the purpose of research and should not be considered a substitute for a thorough evaluation, ongoing care or follow-up by a personal physician. You are not expected to have any benefit from participating in this pre-screening evaluation.

Your participation in this pre-screening for research participation is voluntary. You may decide not to participate or you may leave the pre-screen at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Your alternative is not to participate in this evaluation. Your participation in this pre-screening may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes that may affect you.

Procedures and Safety

The staff at Summit put safety and well-being of our potential research participants as our top priorities. Therefore, we emphasize the importance of the accuracy and completeness of the health information that you provide during the pre-screening process.

You may undergo a brief psychiatric, cognitive and/or physical evaluation which may include the following: a limited physical examination, blood pressure, pulse, body weight, ECG, finger prick blood test, blood and urine testing including but not limited to drug and pregnancy screening. While you may feel faint or lightheaded, or have pain or bruising at the site where blood is drawn, these procedures are of minimal risk and are required for any study being conducted at Summit. If you are deemed a good candidate for a study by the research doctor, you will receive a detailed informed consent for the study into which you may be entered.

While you may feel uncomfortable having your blood pressure measured, standing on a weight scale or providing a urine sample, none of these tests should cause pain. There is also no pain during an ECG. However, the ECG patches may be cold and removing the pads may make your skin red and/or sore. If necessary, a finger prick blood test may cause mild, transient pain with minimal amount of blood collected. If any of these measurements are clinically significant, the Summit physician may ask that you seek the attention of your primary physician before further evaluating you for research. If your urine drug screen and/or urine pregnancy test is positive, you will be notified and the result may exclude you from participating in a study.

Confidentiality of information

Your evaluation will require information about your medical condition. If you are entered into a study, you will be given an additional study-specific consent form describing the use and disclosure of your health information. If you are not eligible for a study, with your permission, your information will be secured in compliance with local and federal requirements.

The information gathered during the pre-screening for a research study may include: Your name, your address, telephone numbers, and birth date. It may also include medical, mental health, medical records/evaluations and current medications, and any pre-screening test results. This pre-screening information will be stored at Summit. We will protect information about you to the best of our ability, but participation in the pre-screening does include the risk of possible loss of confidentiality. Your information will not be shared with other entities, unless required by law.

Per our HIPAA guidelines, if your information is provided for legal reasons and/or to others who are not required to comply with the federal law, your information will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here. If you revoke your authorization for Summit to keep your health information, you must do so in writing and it will be destroyed.

Compensation for participation in a clinical study

The initial pre-screening visit is conducted to determine your eligibility to participate in a research study. You will not be paid for this pre-screening evaluation. If you enter a study, you may receive monetary reimbursement as outlined in the study-specific informed consent document.

Contact for questions

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

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This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions(5)wcgirb.com if

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

CONSENT TO PARTICIPATE IN PRE-SCREENING PROCEDURES

I understand and affirm that neither Summit Headlands LLC nor its affiliated physicians are financially responsible for my medical care. I understand that any additional care, evaluation, or treatment which I may receive at Summit is provided voluntarily and does not imply or establish any agreement by Summit to assume financial responsibility for my ongoing medical care needs.

I have read the above and by signing below, I agree to provide my consent to be interviewed and evaluated by a doctor at Summit. This evaluation will determine my eligibility to participate in a clinical research study and understand that eligibility is determined by a qualified doctor at Summit. This interview and my consent to undergo testing are granted freely and voluntarily. I understand that, unless revoked by me in writing, this authorization will not expire.

It is my responsibility to provide Summit with honest and complete answers to all questions related to my past and/or current health status. I understand the minimal risk the pre-screen evaluation and/or tests present to me.

I understand that I have the right to refuse this consent to undergo pre-screening evaluation by Summit and doing so will prevent my entry into a research study at Summit.

Upon signing this consent and authorization, the signed and dated original document will be provided for me by Summit staff.

If I do not qualify for a study, I am not entitled to any monetary reimbursement.

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_____
NAME OF PARTICIPANT OR LEGALLY AUTHORIZED REPRESENTATIVE (LAR)
(PRINT CLEARLY)

_____ _____
SIGNATURE OF PARTICIPANT OR LAR DATE

_____
RELATIONSHIP OF PARTICIPANT TO LEGALLY AUTHORIZED REPRESENTATIVE (LAR) (if applicable)

_____
PRINTED NAME OF PERSON OBTAINING AUTHORIZATION
(PRINT CLEARLY)

_____ _____
SIGNATURE OF PERSON OBTAINING AUTHORIZATION DATE