GENERAL SCREENING CONSENT FORM

INVESTIGATOR/SITE: Dorian Williams, MD / Todd Crocco, MD
West Virginia University Research Corporation
d.b.a. WVU Clinical and Pharmacologic Research Center (WVU CPRC)
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STUDY-RELATED PHONE NUMBER(S): Dorian Williams, MD / Todd Crocco, MD
304-581-1404
(304) -598-6100 or 1-800-982-8242 (24 hours)

To determine your eligibility for a clinical research study, we need to collect information about you. By signing this consent form, you are permitting us to collect this information. Before you participate in a study, we will give you a consent form with information about that study. Please feel free to ask any questions that you may have.

SCREENING ACTIVITIES: We will ask you questions about your medical history including any medications that you are currently taking or recently stopped. For your safety, please be honest. Procedures could include: Vital Signs (heart rate, blood pressure, breathing rate, and/or temperature), physical examination, Electrocardiogram (ECG), height, weight, urine and fasting blood collections (approximately 20 ml or 1.5 tablespoons) including but not limited to chemistries, blood count, HIV, hepatitis and other communicable diseases, drug and/or alcohol screens, nicotine screen, pregnancy test, and/or hormone levels. Your state law requires that the results of positive tests for HIV and/or Hepatitis be reported to a local health agency. This is the legal obligation of the medical personnel.

We may also do a criminal background check. You will be asked to sign a separate consent form, if this is necessary.

RISKS: Drawing blood may cause pain, bruising, lightheadedness, and rarely infection. Fasting may cause lightheadedness. If you are diabetic or have other medical conditions, side effects from fasting may be more serious, so do not fast without informing us of your current medical conditions. We will discuss with you any risks associated with stopping a current medication.

There is a risk of loss of confidentiality.

BENEFITS: The screening may reveal an existing medical condition. You may be eligible to participate in a clinical research study, which may benefit your health through the testing that is performed.

ALTERNATIVE TREATMENT: This is not a treatment study. Your alternative is to not participate in this study.

PAYMENT AND COSTS: You will receive no payment and neither you nor your insurance company will be charged for the screening.

CONTACTS: If you have any questions about this screening you may contact us at:
Dorian Williams, MD, Todd Crocco MD, or WVU CPRC Staff Member
304-581-1404 or Toll free at 888-991-2772 or 1-800-982-8242 (24 hours)

If you have any questions about the rights of a research subject, you may contact:
Western Institutional Review Board® (WIRB®)
1019 39th Avenue, SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500 E-mail: Help@wirb.com

VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this screening is voluntary. At any time, you may change your mind and choose not to participate, without penalty or loss of benefit unrelated to the screening. We may stop the screening without your consent. There is no guarantee that you will participate.

HIPAA PRIVACY AUTHORIZATION

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

By signing this authorization, you are giving your authorization (permission) to WVU Clinical and Pharmacologic Research Center (WVU CPRC) to consider you for participation in a research study and to obtain, use and disclose (share) health information about you.

What information may be obtained, used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records, Research records, Records about phone calls made as part of this research, Records about your study visits.

Who may obtain, use and give out information about you?

- The study doctor and the study staff of the WVU CPRC.

Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are working for or with the sponsor, or owned by the sponsor
- The U.S. Food and Drug Administration (FDA)
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research, to study the results, and to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in research studies at WVUCPRC.

May I review or copy my information?

- Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.

Initials: _____

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

- There is a risk that your information will be given to others without your permission.

CONSENT: I have read this entire consent form. I have had a chance to ask questions, and my questions have all been answered to my satisfaction.

By signing this consent form, I agree to participate in the screening. I give permission to use the resulting information to determine my eligibility for a clinical research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent form for the purposes described above.

By signing this consent form, I have not waived any of the legal rights that I have as a subject in a research study.

Subject Name (Please print)	Date
Signature of Subject	Time
Person Conducting Informed Consent Discussion (Please Print)	Date
Signature of Person Conducting Informed Consent Discussion	Time