INFORMED CONSENT FORM SWIFT-CORE-101 PRE-SCREENING STUDY

Sponsor / Study Title:	**Brooklyn Clinical Research / "Triage Survey for Cardiovascular, Obesity, and Related Endocrine Trial Eligibility (SWIFT-CORE-101)"**
Protocol Number:	**CORE042024**
Principal Investigator: (Study Doctor)	**Ammara Mushtaq, MD**
Telephone:	**929-552-2442** **929-203-5879 (24 Hour)**
Address:	**Brooklyn Clinical Research** **150 Lenox Rd** **Brooklyn, NY 11226**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

INTRODUCTION AND PURPOSE

You are being invited to volunteer for this general screening study because you have expressed interest in participating in a clinical study. We will collect information about your demographic and medical history. You will also meet with a researcher to discuss your symptoms and medications. These assessments will help the study investigators know which studies you could participate in.

SCREENING PROCEDURES

If you decide to participate in this study, the researchers will do the following:

- Collect medical history and what medications you are taking.
- Collect demographic information.

If necessary, the study investigators may require additional information and do the following:

- Measure your height, weight, abdominal circumference, blood pressure, and heart rate.
- Collect a urine sample to detect drugs or pregnancy.
- Conduct a finger prick HbA1c test.
- Obtain a preferably fasting blood draw sample that will detect the following:
    - Comprehensive Metabolic Panel
    - Creatine/eGFR Panel
    - HbA1c Panel
    - Uric Acid Panel
    - CBC Panel
    - hsCRP Panel
    - Lipid Profile

HOW LONG THE SCREENING STUDY WILL LAST

The screening process will last approximately 1 hour.

INFORMATION ABOUT STUDY PARTICIPATION

You cannot participate in this study if you are pregnant or breastfeeding, or if you are misusing drugs or alcohol.

WILL I HAVE TO PAY FOR ANYTHING

All screening office visits required will be provided without charge to you.

WILL I BE PAID FOR BEING IN THE STUDY

You will be compensated up to $50.00 USD for your participation and travel upon completion of any portion of the pre-screening office visit.

POSSIBLE RISKS AND BENEFITS OF THE SCREENING

The risks of this study are essentially the same as those of a general medical exam performed in a doctor's private office. A blood draw may result in minor discomfort, swelling, and bruising, which is usually transient. There may be other risks that are unknown. The benefits of this study are information about your health and a chance to help others if you are eligible for and choose to participate in a clinical study.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes only. The only alternative is to not participate in this study.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY

Your records will be kept private. The only exceptions are that your records may be sent to:

- Advarra Institutional Review Board (IRB)
- Regulatory authorities, including inspection by the United Stated Food and Drug Administration (FDA)
- Third-party databases, existing solely to check whether you have participated in a prior study
- Staff and business associates of Brooklyn Clinical Research

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

THIRD-PARTY DATABASES OF PRIOR STUDY PARTICIPATION

In most cases, a person cannot participate in this study if that person has participated in another study. To check if you match with a prior participant, we enter some information about you into encoded databases. This information is the first three letters of your first and last name, your gender, date of birth, and the last digits of your license. This information remains in the database even after this study is completed. To protect your information, your data will be stored in a de-identified format. If you or someone else with closely matching personal data applies to participate in a research study, the information above in addition to your dates of research participation and the study indication may be shared with the researchers conducting that study to verify your eligibility. If most of your personal information is identified as a match, you may not be allowed to participate. You may contact the study investigator at any time to review your data or to take away permission to use and disclose your data.

LEGAL RIGHTS

You will not lose any of your legal rights by signing and dating this consent form.

FUNDING AND CONFLICT OF INTEREST DISCLOSURE

Brooklyn Clinical Research designed this general screening study, drafted the study plan, and is providing money so that study investigators can conduct the study. If you complete this study, you may later be eligible to participate in a separate research study. Many of these separate studies are funded by pharmaceutical companies. Should you choose to participate in a separate study funded by a pharmaceutical company or another Sponsor, the research site conducting that study and its owners will benefit financially from your participation. The study investigator also serves as the study investigator of industry-sponsored studies conducted at the research site. As a result, the investigators may benefit financially from a successful study. Please speak with the study investigator if you have questions about this.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures.

Please contact the study investigator 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 research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00078993.

VOLUNTEERING TO BE IN THE SCREENING STUDY

It is your choice if you wish to participate in this screening study. No one can force you to participate. You can choose not to participate, or leave the screening at any time, without penalty or loss of benefits to which you are otherwise entitled. You can still get healthcare in the future. If you have questions not answered in this consent form, ask the study staff. Your signature below provides your consent for participation in the study.

The study investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it is in your best interest.
- You do not consent to continue in the study after being told of changes in the research that may

affect you.

CONSENT

I have read and understand the information in this informed consent document. I have had a chance to ask questions, and all of them have been answered. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed and dated consent document.

_____
Printed Name of Screening Participant

_____
Signature of Screening Participant Date

_____
Printed Name of Legally Authorized Representative

_____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

_____
Printed Name of Study Investigator Explaining Consent Form

_____
Signature of Study Investigator Explaining Consent Form Date

You will be given a copy of this consent form once completed.