

PRE-SCREENING INFORMATION AND CONSENT FORM

INVESTIGATOR:

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You have agreed to be a possible subject in a research project. There are certain procedures, which you may be asked to undergo to help us determine if you will be eligible for a study. This pre-screening consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

PURPOSE

This consent form is to allow us to determine your eligibility for a study. By signing this pre-screening consent form, you are not agreeing to participate in a research study, but are only agreeing to have certain procedures performed which will be described below. If you are eligible for a study and voluntarily agree to participate, you will be asked to sign a different consent form, which will be study specific and will contain complete information about the study and the study procedures.

SCREENING PROCEDURES

These screening procedures could include some or all of the following:

- **HEALTH HISTORY:** You will be asked questions about your overall health, your asthma or other conditions, and about medications you may be taking for these conditions including those prescribed by your doctor and over-the-counter medications.
- **PHYSICAL EXAMINATION:** A limited physical examination may be performed.
- **VITAL SIGNS:** Your blood pressure, pulse, heart rate, respiratory rate, temperature, height and weight may be taken and recorded.
- **PULMONARY FUNCTION TESTING:** A pulmonary function test (PFT) is done by blowing into a machine to evaluate how well your lungs are

working. This test will measure how much air you inhale and how rapidly you can move that air out of your lungs. You may be asked to blow into the machine before and after inhaling 2-4 puffs of a bronchodilator, a substance which opens the bronchial tubes. This helps determine your general lung function level without medication, and how easily any narrowing of your bronchial tubes can be opened up or “reversed”. Bronchodilator medications can cause fast heart rate and high blood pressure, which carry increased risk for patients with underlying cardiac and vascular disease.

- **SKIN TESTING:** Skin testing is done by placing drops of fluid on your arm that contain things you might be allergic to (like cat and dog allergens), and then pricking the skin through that drop with a needle. If you are sensitive to that allergen, some redness and swelling (classically, a “hive”) will develop at the site within 15-20 minutes. Occasionally intradermal tests may be needed. These are more sensitive tests that require injecting a small amount of fluid containing the allergen underneath the skin. Administering these test, frequently stings for a few seconds. Skin testing may cause discomfort from itching or swelling at the site. The itching or swelling usually goes away within 30 to 60 minutes after the skin test, although it sometimes last from 24 to 48 hours. Symptoms such as itching all over the body, sneezing, and eyelid swelling occur rarely with skin testing. Your doctor can treat a reaction if necessary. Although very rare, skin testing can result in a severe allergic reaction (anaphylactic shock) that can be fatal.
- **MEDICATION CHANGES:** You may be on medications that are not allowed during the course of a research study. **Do not change, withhold, or stop any medication on your own; you will be instructed when to do so by our study personnel.** Any instructions for you to withhold, discontinue, or change medications will be given after reviewing your health status and you consent to be in a research study.

If the study doctor or the person designated by the study doctor to discuss the study with you determines that you are eligible to screen for a particular study, you will be given a consent form specifically for that study. This consent form will describe the study in detail and a study coordinator or the study doctor will go over it with you. You will be given time to review the consent form and an opportunity to ask and receive answers to any questions you may have regarding the study. After your questions have been answered, if you decide you would like to participate in the study, you will need to sign the informed consent to show that you want to participate in the study and that your questions have been answered to your satisfaction. A “screening visit” will be scheduled. At this visit other procedures may be done; these procedures will be described in the informed consent.

If the study doctor or designee determines that it is not in your best interest to participate in a study at this time because of an acute infection, unstable asthma or other health issues, if appropriate, medications you are currently taking could be changed. Or if

necessary, medications may be prescribed to help you temporarily. If you are not a patient in our clinic and we do not ordinarily have responsibility for your care, you will be referred back to your primary care physician for follow-up and further treatment if necessary.

QUESTIONS

If you have any questions about this pre-screening, contact:

Dr Andrew J. Pedinoff, MD	at	(609)921-2202
Study Doctor's Name		Study Doctor's Telephone Number

If you have any questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone 1-800-562-4789

WIRB is a group of people who perform independent reviews of research in order to safeguard the health and safety of research subjects.

You will receive a signed and dated copy of this consent form for your records. Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

VOLUNTARY PARTICIPATION

You do not have to do these pre-screening procedures. Your care at Princeton Center for Clinical Research will not be affected in any way by your decision. The results of your test do not guarantee your acceptance into the research program, but may be used to help determine your eligibility for enrollment. Neither you nor your insurance company will incur any charge for these tests.

CONFIDENTIALITY

If you are selected to participate in a research study, the medical screening exam will become part of the record for that study. Information from clinical research studies is submitted to the sponsor and to the U.S. Food and Drug Administration (FDA) and it may be submitted to the governmental agencies in other countries. Medical records which identify you, and the consent form signed by you, will be inspected by the sponsor,

and may be inspected and/or copied by the FDA, the Department of Health and Human Services (DHHS) governmental agencies in other countries, and the Western Institutional Review Board (WIRB[®]).

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this pre-screening study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

SUBJECT CONSENT

I have read the above information. I have been offered an opportunity to ask questions and I have received answers that satisfy those questions. I volunteer to undergo these pre-screening procedures. I agree to possible future contact in regard to my participation in a research study and I agree that you may enter my name, phone number, diagnosis, medications and test results into your database for future contact. This information will not be sold or used by anyone else other than Princeton Center for Clinical Research.

I understand I have the right to inspect the disclosed information at any time. This authorization has no expiration date. I understand that I may revoke this authorization at any time, except to the extent that action has already been taken in reliance upon it, by giving written notice to the health care provider or record keeper. A photocopy, or exact reproduction of this signed authorization shall have the same force and effect as the original.

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

_____	_____	_____
Subject's Name (Printed)	Subject's Signature	Date
_____		_____
Person Conducting Informed Consent		Date
_____		_____
Investigator's Signature (if different from above)		Date